

117TH CONGRESS  
2D SESSION

# S. 3799

To prepare for, and respond to, existing viruses, emerging new threats,  
and pandemics.

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## IN THE SENATE OF THE UNITED STATES

MARCH 10 (legislative day, MARCH 7), 2022

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

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## A BILL

To prepare for, and respond to, existing viruses, emerging  
new threats, and pandemics.

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 “Prepare for and Respond to Existing Viruses, Emerging  
6 New Threats, and Pandemics Act” or the “PREVENT  
7 Pandemics Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—STRENGTHENING FEDERAL AND STATE  
PREPAREDNESS

Subtitle A—Federal Leadership and Accountability

- Sec. 101. Comprehensive review of the COVID–19 response.
- Sec. 102. Appointment and authority of the Director of the Centers for Disease Control and Prevention.
- Sec. 103. Additional provisions related to the Centers for Disease Control and Prevention.
- Sec. 104. Public health and medical preparedness and response coordination.
- Sec. 105. Strengthening public health communication.
- Sec. 106. Office of Pandemic Preparedness and Response Policy.

Subtitle B—State and Local Readiness

- Sec. 111. Improving State and local public health security.
- Sec. 112. Supporting access to mental health and substance use disorder services during public health emergencies.
- Sec. 113. Trauma care reauthorization.
- Sec. 114. Assessment of containment and mitigation of infectious diseases.

TITLE II—IMPROVING PUBLIC HEALTH PREPAREDNESS AND  
RESPONSE CAPACITY

Subtitle A—Addressing Disparities and Improving Public Health Emergency  
Responses

- Sec. 201. Addressing social determinants of health and improving health outcomes.
- Sec. 202. National Academies of Sciences, Engineering, and Medicine report.

Subtitle B—Improving Public Health Data

- Sec. 211. Modernizing biosurveillance capabilities and infectious disease data collection.
- Sec. 212. Genomic sequencing, analytics, and public health surveillance of pathogens.
- Sec. 213. Supporting public health data availability and access.
- Sec. 214. Epidemic forecasting and outbreak analytics.
- Sec. 215. Report on CDC data portal.
- Sec. 216. Public health data transparency.

Subtitle C—Revitalizing the Public Health Workforce

- Sec. 221. Improving recruitment and retention of the frontline public health workforce.
- Sec. 222. Awards to support community health workers and community health.
- Sec. 223. Improving public health emergency response capacity.
- Sec. 224. Extension of authorities to support health professional volunteers at community health centers.
- Sec. 225. Increasing educational opportunities for allied health professions.
- Sec. 226. Public Health Service Corps annual and sick leave.

Subtitle D—Improving Public Health Responses

- Sec. 231. Centers for public health preparedness and response.
- Sec. 232. Vaccine distribution plans.

Sec. 233. Coordination and collaboration regarding blood supply.

TITLE III—ACCELERATING RESEARCH AND COUNTERMEASURE  
DISCOVERY

Subtitle A—Fostering Research and Development and Improving Coordination

- Sec. 301. Research and activities related to long-term health effects of SARS-CoV-2 infection.
- Sec. 302. Research centers for pathogens of pandemic concern.
- Sec. 303. Improving medical countermeasure research coordination.
- Sec. 304. Accessing specimen samples and diagnostic tests.

Subtitle B—Improving Biosafety and Biosecurity

- Sec. 311. Improving control and oversight of select biological agents and toxins.
- Sec. 312. Strategy for Federal high-containment laboratories.
- Sec. 313. National Science Advisory Board for Biosecurity.
- Sec. 314. Research to improve biosafety.
- Sec. 315. Federally-funded research with enhanced pathogens of pandemic potential.

Subtitle C—Preventing Undue Foreign Influence in Biomedical Research

- Sec. 321. Foreign talent programs.
- Sec. 322. Securing identifiable, sensitive information.
- Sec. 323. Duties of the Director.
- Sec. 324. Protecting America's biomedical research enterprise.
- Sec. 325. GAO Study.
- Sec. 326. Report on progress to address undue foreign influence.

TITLE IV—MODERNIZING AND STRENGTHENING THE SUPPLY  
CHAIN FOR VITAL MEDICAL PRODUCTS

- Sec. 401. Warm base manufacturing capacity for medical countermeasures.
- Sec. 402. Supply chain considerations for the Strategic National Stockpile.
- Sec. 403. Strategic National Stockpile equipment maintenance.
- Sec. 404. Improving transparency and predictability of processes of the Strategic National Stockpile.
- Sec. 405. Improving supply chain flexibility for the Strategic National Stockpile.
- Sec. 406. Reimbursement for certain supplies.
- Sec. 407. Action reporting on stockpile depletion.
- Sec. 408. Provision of medical countermeasures to Indian programs and facilities.
- Sec. 409. Grants for State strategic stockpiles.

TITLE V—ENHANCING DEVELOPMENT AND COMBATING  
SHORTAGES OF MEDICAL PRODUCTS

Subtitle A—Development and Review

- Sec. 501. Advancing qualified infectious disease product innovation.
- Sec. 502. Modernizing clinical trials.
- Sec. 503. Accelerating countermeasure development and review.
- Sec. 504. Third party test evaluation during emergencies.
- Sec. 505. Facilitating the use of real world evidence.
- Sec. 506. Platform technologies.

- Sec. 507. Increasing EUA decision transparency.  
 Sec. 508. Improving FDA guidance and communication.  
 Sec. 509. GAO study and report on hiring challenges at FDA.

Subtitle B—Mitigating Shortages

- Sec. 511. Ensuring registration of foreign drug and device manufacturers.  
 Sec. 512. Extending expiration dates for certain drugs.  
 Sec. 513. Unannounced foreign facility inspections pilot program.  
 Sec. 514. Combating counterfeit devices.  
 Sec. 515. Strengthening medical device supply chains.  
 Sec. 516. Preventing medical device shortages.  
 Sec. 517. Remote records assessments for medical devices.  
 Sec. 518. Advanced manufacturing technologies designation pilot program.  
 Sec. 519. Technical corrections.

1 **TITLE I—STRENGTHENING FED-**  
 2 **ERAL AND STATE PREPARED-**  
 3 **NESS**

4 **Subtitle A—Federal Leadership**  
 5 **and Accountability**

6 **SEC. 101. COMPREHENSIVE REVIEW OF THE COVID-19 RE-**  
 7 **SPONSE.**

8 (a) ESTABLISHMENT OF TASK FORCE.—There is es-  
 9 tablished in the legislative branch a task force to be known  
 10 as the “National Task Force on the Response of the  
 11 United States to the COVID–19 Pandemic” (referred to  
 12 in this section as the “Task Force”).

13 (b) PURPOSES.—The purposes of the Task Force are  
 14 to—

15 (1) examine, assess, and report upon the  
 16 United States’ preparedness for, and response to,  
 17 the COVID–19 pandemic, including—

1 (A) the initial Federal, State, local, and  
2 territorial responses in the United States;

3 (B) the ongoing Federal, State, local, and  
4 territorial responses in the United States, in-  
5 cluding the activities, policies, and decisions of  
6 the Trump Administration and the Biden Ad-  
7 ministration;

8 (C) the impact of the pandemic on public  
9 health and health care systems; and

10 (D) the initial outbreak in Wuhan, China,  
11 including efforts to determine the potential  
12 causes for the emergence of the SARS-CoV-2  
13 virus, and Federal actions to mitigate its spread  
14 internationally;

15 (2) build upon existing or ongoing evaluations  
16 and avoid unnecessary duplication, by reviewing the  
17 findings, conclusions, and recommendations of other  
18 appropriate task forces, committees, commissions, or  
19 entities established by other public or nonprofit pri-  
20 vate entities related to the United States' prepared-  
21 ness for, and response to, the COVID-19 pandemic;

22 (3) identify gaps in public health preparedness  
23 and medical response policies, processes, and activi-  
24 ties, including disparities in COVID-19 infection  
25 and mortality rates among people of color, older

1 adults, people with disabilities, and other vulnerable  
2 or at-risk groups, and how such gaps impacted the  
3 ability of the United States to respond to the  
4 COVID–19 pandemic; and

5 (4) submit a report to the President and to  
6 Congress on its findings, conclusions, and rec-  
7 ommendations to improve the United States pre-  
8 paredness for, and response to, future public health  
9 emergencies, including a public health emergency re-  
10 sulting from an emerging infectious disease.

11 (c) COMPOSITION OF TASK FORCE; MEETINGS.—

12 (1) MEMBERS.—The Task Force shall be com-  
13 posed of 12 members, of whom—

14 (A) 1 member shall be appointed by the  
15 majority leader of the Senate;

16 (B) 1 member shall be appointed by the  
17 minority leader of the Senate;

18 (C) 2 members shall be appointed by the  
19 chair of the Committee on Health, Education,  
20 Labor, and Pensions of the Senate;

21 (D) 2 members shall be appointed by the  
22 ranking member of the Committee on Health,  
23 Education, Labor, and Pensions of the Senate;

24 (E) 1 member shall be appointed by the  
25 Speaker of the House of Representatives;

1 (F) 1 member shall be appointed by the  
2 minority leader of the House of Representa-  
3 tives;

4 (G) 2 members shall be appointed by the  
5 chair of the Committee on Energy and Com-  
6 merce of the House of Representatives; and

7 (H) 2 members shall be appointed by the  
8 ranking member of the Committee on Energy  
9 and Commerce of the House of Representatives.

10 (2) CHAIR AND VICE CHAIR.—Not later than 30  
11 days after the date on which all members of the  
12 Task Force are appointed under paragraph (1), such  
13 members shall meet to elect a Chair and Vice Chair  
14 from among such members. The Chair and Vice  
15 Chair shall each be elected to serve upon an affirma-  
16 tive vote from 8 members of the Task Force. The  
17 Chair and Vice Chair shall not be registered mem-  
18 bers of the same political party.

19 (3) QUALIFICATIONS.—

20 (A) POLITICAL PARTY AFFILIATION.—Not  
21 more than 6 members of the Task Force shall  
22 be registered members of the same political  
23 party.

24 (B) NONGOVERNMENTAL APPOINTEES.—

25 An individual appointed to the Task Force may

1 not be an officer or employee of the Federal  
2 Government or any State, local, Tribal, or terri-  
3 torial government.

4 (C) QUALIFICATIONS.—It is the sense of  
5 Congress that individuals appointed to the Task  
6 Force should be highly qualified citizens of the  
7 United States. Members appointed under para-  
8 graph (1) may include individuals with expertise  
9 in—

10 (i) public health, health disparities  
11 and at-risk populations, medicine, and re-  
12 lated fields;

13 (ii) State, local, Tribal, or territorial  
14 government, including public health and  
15 medical preparedness and response and  
16 emergency management and other relevant  
17 public administration;

18 (iii) research regarding, or the devel-  
19 opment, manufacturing, distribution, and  
20 regulation of, medical products;

21 (iv) national security and foreign rela-  
22 tions, including global health; and

23 (v) commerce, including transpor-  
24 tation, supply chains, and small business.



1           (4) DEADLINE FOR APPOINTMENT.—All mem-  
2           bers of the Task Force shall be appointed not later  
3           than 90 days after the date of enactment of this  
4           Act.

5           (5) MEETINGS.—The Task Force shall meet  
6           and begin the operations of the Task Force as soon  
7           as practicable. After its initial meeting, the Task  
8           Force shall meet upon the call of the Chair and Vice  
9           Chair or 8 of its members.

10          (6) QUORUM; VACANCIES.—

11           (A) QUORUM.—Eight members of the  
12           Task Force shall constitute a quorum.

13           (B) VACANCIES.—Any vacancy in the Task  
14           Force shall not affect its powers, but shall be  
15           filled in the same manner in which the original  
16           appointment was made.

17          (d) FUNCTIONS OF TASK FORCE.—The functions of  
18          the Task Force are to—

19           (1) conduct a review that—

20           (A) examines the initial outbreak of the  
21           SARS-CoV-2 virus in Wuhan, China, includ-  
22           ing—

23           (i) engaging with willing partner gov-  
24           ernments and global experts;

1 (ii) seeking access to relevant records;

2 and

3 (iii) examining the potential causes of  
4 the emergence and source of the virus;

5 (B) examines the United States prepara-  
6 tion for, and response to, the COVID–19 pan-  
7 demic, including—

8 (i) relevant laws, policies, regulations,  
9 and processes that were in place prior to,  
10 or put into place during, the public health  
11 emergency declared by the Secretary of  
12 Health and Human Services under section  
13 319 of the Public Health Service Act (42  
14 U.S.C. 247d) with respect to COVID–19,  
15 including any that are put into place re-  
16 lated to such public health emergency after  
17 the date of enactment of this Act and prior  
18 to the issuance of the final report pursuant  
19 to subsection (j)(2);

20 (ii) relevant actions taken by, and co-  
21 ordination between, Federal, State, local,  
22 Tribal, and territorial governments, non-  
23 governmental organizations, and inter-  
24 national organizations on preparedness and  
25 response efforts, including coordination be-

1           tween governments and other public and  
2           private entities, during the—

3                   (I) initial response in the United  
4                   States;

5                   (II) response during the Trump  
6                   Administration; and

7                   (III) ongoing response during the  
8                   Biden Administration;

9                   (iii) communication of public health  
10                  and scientific information related to the  
11                  COVID–19 pandemic, including processes  
12                  for the development, approval, and dis-  
13                  semination of Federal public health and  
14                  other relevant public health or scientific  
15                  guidance;

16                  (iv) actions taken to support the de-  
17                  velopment, manufacturing, and distribution  
18                  of medical countermeasures and related  
19                  medical supplies to prevent, detect, and  
20                  treat COVID–19; and

21           (C) may include assessments relating to—

22                   (i) the capacity and capabilities of  
23                   Federal, State, local, Tribal, and territorial  
24                   governments to respond to the COVID–19  
25                   pandemic;

1 (ii) the capacity and capabilities of  
2 health care facilities and the health care  
3 workforce to respond to the COVID–19  
4 pandemic;

5 (iii) medical countermeasure research  
6 and development and the supply chains of  
7 medical products necessary to respond to  
8 the COVID–19 pandemic;

9 (iv) international preparedness for  
10 and response to COVID–19, and Federal  
11 decision-making processes related to new  
12 global health threats;

13 (v) containment and mitigation meas-  
14 ures related to domestic and international  
15 travel in response to COVID–19; and

16 (vi) the impact of the COVID–19 pan-  
17 demic and related mitigation efforts on  
18 hard-to-reach and at-risk or underserved  
19 populations, including related health dis-  
20 parities;

21 (2) identify, review, and evaluate the lessons  
22 learned from the COVID–19 pandemic, including ac-  
23 tivities to prepare for, and respond to, future poten-  
24 tial pandemics and related public health emer-  
25 gencies; and

1           (3) submit to the President and Congress such  
2 reports as are required by this Act containing such  
3 findings, conclusions, and recommendations as the  
4 Task Force shall determine.

5 (e) POWERS OF TASK FORCE.—

6           (1) HEARINGS.—The Task Force may—

7           (A) hold such hearings and sit and act at  
8 such times and places, take such testimony, re-  
9 ceive such evidence as determined by the Chair  
10 and Vice Chair, and administer such oaths as  
11 the Task Force or a designated member, as de-  
12 termined by the Chair or Vice Chair, may de-  
13 termine advisable to be necessary to carry out  
14 the functions of the Task Force; and

15           (B) subject to paragraph (2)(A), require,  
16 by subpoena or otherwise, the attendance and  
17 testimony of such witnesses and the production  
18 of such books, records, correspondence, memo-  
19 randa, papers, and documents, as the person  
20 described in paragraph (2)(A)(i) may determine  
21 advisable.

22           (2) SUBPOENAS.—

23           (A) ISSUANCE.—

24           (i) IN GENERAL.—A subpoena may be  
25 issued under this subsection only—

1 (I) by the agreement of the Chair  
2 and the Vice Chair; or

3 (II) by the affirmative vote of 9  
4 members of the Task Force.

5 (ii) SIGNATURE.—Subpoenas issued  
6 under this subsection may be issued under  
7 the signature of the Chair or any member  
8 designated by a majority of the Task  
9 Force, and may be served by any person  
10 designated by the Chair or by a member  
11 designated by agreement of the majority of  
12 the Task Force.

13 (B) ENFORCEMENT.—In the case of contu-  
14 macy or failure to obey a subpoena issued  
15 under subsection, the United States district  
16 court for the judicial district in which the sub-  
17 poenaed person resides, is served, or may be  
18 found, or where the subpoena is returnable,  
19 may issue an order requiring such person to ap-  
20 pear at any designated place to testify or to  
21 produce documentary or other evidence. Any  
22 failure to obey the order of the court may be  
23 punished by the court as a contempt of that  
24 court.

1           (3) CONTRACTING.—The Task Force may, to  
2 such extent and in such amounts as are provided in  
3 appropriation Acts, enter into contracts to enable  
4 the Task Force to discharge its duties under this  
5 Act.

6           (4) INFORMATION FROM FEDERAL AGENCIES.—

7           (A) IN GENERAL.—The Task Force may  
8 access from any executive department, bureau,  
9 agency, board, commission, office, independent  
10 establishment, or instrumentality of the Federal  
11 Government, such information, documents, sug-  
12 gestions, estimates, and statistics as the Task  
13 Force considers necessary to carry out this sec-  
14 tion.

15           (B) PROVISION OF INFORMATION.—On  
16 written request of the Chair, each department,  
17 bureau, agency, board, commission, office, inde-  
18 pendent establishment, or instrumentality shall,  
19 to the extent authorized by law, provide such  
20 information to the Task Force.

21           (C) RECEIPT, HANDLING, STORAGE, AND  
22 DISSEMINATION.—Information shall only be re-  
23 ceived, handled, stored, and disseminated by  
24 members of the Task Force and its staff con-

1           sistent with all applicable statutes, regulations,  
2           and executive orders.

3           (5) ASSISTANCE FROM FEDERAL AGENCIES.—

4                   (A) GENERAL SERVICES ADMINISTRA-  
5           TION.—On request of the Chair and Vice Chair,  
6           the Administrator of General Services Adminis-  
7           tration shall provide to the Task Force, on a re-  
8           imbursable basis, administrative support and  
9           other assistance necessary for the Task Force  
10          to carry out its duties.

11                   (B) OTHER DEPARTMENTS AND AGEN-  
12          CIES.—In addition to the assistance provided  
13          for in subparagraph (A), departments and  
14          agencies of the United States may provide to  
15          the Task Force such assistance as such depart-  
16          ments and agencies may determine advisable  
17          and as authorized by law.

18           (6) DONATIONS.—The Task Force may accept,  
19          use, and dispose of gifts or donations of services or  
20          property. Not later than 5 days after the acceptance  
21          of a donation under this subsection, the Task Force  
22          shall publicly disclose—

23                   (A) the name of the entity that provided  
24          such donation;



1 (B) the service or property provided  
2 through such donation;

3 (C) the value of such donation; and

4 (D) how the Task Force plans to use such  
5 donation.

6 (7) POSTAL SERVICES.—The Task Force may  
7 use the United States mails in the same manner and  
8 under the same conditions as a department or agen-  
9 cy of the United States.

10 (f) APPLICABILITY OF FEDERAL ADVISORY COM-  
11 MITTEE ACT.—

12 (1) IN GENERAL.—The Federal Advisory Com-  
13 mittee Act (5 U.S.C. App.) shall apply to the Task  
14 Force.

15 (2) PUBLIC MEETINGS AND RELEASE OF PUB-  
16 LIC VERSIONS OF REPORTS.—The Task Force  
17 shall—

18 (A) hold public hearings and meetings to  
19 the extent appropriate; and

20 (B) release public versions of the reports  
21 required under paragraph (1) and (2) of sub-  
22 section (j).

23 (3) PUBLIC HEARINGS.—Any public hearings of  
24 the Task Force shall be conducted in a manner con-  
25 sistent with the protection of information provided

1 to or developed for or by the Task Force as required  
2 by any applicable statute, regulation, or Executive  
3 order.

4 (g) STAFF OF TASK FORCE.—

5 (1) IN GENERAL.—

6 (A) APPOINTMENT AND COMPENSATION.—

7 The Chair of the Task Force, in agreement  
8 with the Vice Chair, in accordance with rules  
9 agreed upon by the Task Force, may appoint  
10 and fix the compensation of a staff director and  
11 such other personnel as may be necessary to en-  
12 able the Task Force to carry out its functions,  
13 without regard to the provisions of title 5,  
14 United States Code, governing appointments in  
15 the competitive service, and without regard to  
16 the provisions of chapter 51 and subchapter III  
17 of chapter 53 of such title relating to classifica-  
18 tion and General Schedule pay rates, except  
19 that no rate of pay fixed under this subsection  
20 may exceed the equivalent of that payable for a  
21 position at level V of the Executive Schedule  
22 under section 5316 of title 5, United States  
23 Code.

24 (B) PERSONNEL AS FEDERAL EMPLOY-  
25 EES.—

1 (i) IN GENERAL.—The staff director  
2 and any personnel of the Task Force who  
3 are employees shall be employees under  
4 section 2105 of title 5, United States  
5 Code, for purposes of chapters 63, 81, 83,  
6 84, 85, 87, 89, and 90 of that title.

7 (ii) MEMBERS OF TASK FORCE.—  
8 Clause (i) shall not be construed to apply  
9 to members of the Task Force.

10 (2) DETAILEES.—Upon request of the Chair  
11 and Vice Chair of the Task Force, the head of any  
12 executive department, bureau, agency, board, com-  
13 mission, office, independent establishment, or instru-  
14 mentality of the Federal Government employee may  
15 detail, without reimbursement, any of its personnel  
16 to the Task Force to assist in carrying out its duties  
17 under this section. Any such detailee shall be with-  
18 out interruption or loss of civil service status or  
19 privilege.

20 (3) CONSULTANT SERVICES.—The Task Force  
21 is authorized to procure the services of experts and  
22 consultants in accordance with section 3109 of title  
23 5, United States Code, but at rates not to exceed the  
24 daily rate paid a person occupying a position at level

1 IV of the Executive Schedule under section 5315 of  
2 title 5, United States Code.

3 (h) COMPENSATION AND TRAVEL EXPENSES.—Each  
4 member of the Task Force shall serve without compensa-  
5 tion, but shall receive travel expenses, including per diem  
6 in lieu of subsistence, at rates authorized for an employee  
7 of an agency under subchapter I of chapter 57 of title  
8 5, United States Code.

9 (i) SECURITY CLEARANCES FOR TASK FORCE MEM-  
10 BERS AND STAFF.—The appropriate Federal agencies or  
11 departments shall cooperate with the Task Force in expe-  
12 ditiously providing to the Task Force members and staff  
13 appropriate security clearances, consistent with existing  
14 procedures and requirements. No person shall be provided  
15 with access to classified information under this section  
16 without the appropriate security clearances.

17 (j) REPORTS OF TASK FORCE; TERMINATION.—

18 (1) INTERIM REPORT.—Not later than 180  
19 days after the date of enactment of this Act, the  
20 Task Force shall submit to the President, the Com-  
21 mittee on Health, Education, Labor, and Pensions  
22 of the Senate, and the Committee on Energy and  
23 Commerce of the House of Representatives an in-  
24 terim report containing such findings, conclusions,  
25 and recommendations as have been agreed to by 8

1 members of the Task Force. Such interim report  
2 shall be made available online in a manner that does  
3 not compromise national security.

4 (2) FINAL REPORT.—

5 (A) IN GENERAL.—Not later than 18  
6 months after the date on which the last member  
7 of the Task Force is appointed, the Task Force  
8 shall submit to the President, the Committee on  
9 Health, Education, Labor, and Pensions of the  
10 Senate, and the Committee on Energy and  
11 Commerce of the House of Representatives a  
12 final report containing such findings, conclu-  
13 sions, and recommendations as have been  
14 agreed to by 8 members of the Task Force. The  
15 final report shall be made available online in a  
16 manner that does not compromise national se-  
17 curity.

18 (B) EXTENSIONS.—

19 (i) IN GENERAL.—The submission  
20 and publication of the final report, as de-  
21 scribed in subparagraph (A), may be de-  
22 layed by 6 months upon the agreement of  
23 8 members of the Task Force.

24 (ii) NOTIFICATION.—The Task Force  
25 shall notify the President, the Committee

1 on Health, Education, Labor, and Pen-  
2 sions of the Senate, the Committee on En-  
3 ergy and Commerce of the House of Rep-  
4 resentatives, and the public of any exten-  
5 sion granted under clause (i).

6 (C) SPECIAL RULES AND CONSIDER-  
7 ATIONS.—

8 (i) RULE OF CONSTRUCTION.—Noth-  
9 ing in this subsection shall be construed as  
10 authorizing the Task Force to publicly dis-  
11 close information otherwise prohibited from  
12 disclosure by law.

13 (ii) SPECIAL TIMING CONSIDER-  
14 ATIONS.—Notwithstanding any other pro-  
15 vision of this section, the Task Force shall  
16 not publish or make available any interim  
17 or final report during the during the 60-  
18 day periods ending November 8, 2022, and  
19 November 5, 2024.

20 (3) TERMINATION.—

21 (A) IN GENERAL.—The Task Force, and  
22 all the authorities of this section, shall termi-  
23 nate 60 days after the date on which the final  
24 report is submitted under paragraph (2).

1 (B) ADMINISTRATIVE ACTIVITIES BEFORE  
2 TERMINATION.—The Task Force may use the  
3 60-day period referred to in subparagraph (A)  
4 for the purpose of concluding its activities, in-  
5 cluding providing testimony to committees of  
6 Congress concerning its reports and dissemi-  
7 nating the final report.

8 (k) FUNDING.—

9 (1) AUTHORIZATION OF APPROPRIATIONS.—  
10 There is authorized to be appropriated to carry out  
11 this section, a total of \$3,000,000 for fiscal years  
12 2023 and 2024.

13 (2) DURATION OF AVAILABILITY.—Amounts  
14 made available to the Task Force under paragraph  
15 (1) shall remain available until the termination of  
16 the Task Force.

17 **SEC. 102. APPOINTMENT AND AUTHORITY OF THE DIREC-**  
18 **TOR OF THE CENTERS FOR DISEASE CON-**  
19 **TROL AND PREVENTION.**

20 (a) IN GENERAL.—Part A of title III of the Public  
21 Health Service Act (42 U.S.C. 241 et seq.) is amended  
22 by inserting after section 304 the following:

1 **“SEC. 305. APPOINTMENT AND AUTHORITY OF THE DIREC-**  
2 **TOR OF THE CENTERS FOR DISEASE CON-**  
3 **TROL AND PREVENTION.**

4 “(a) IN GENERAL.—The Centers for Disease Control  
5 and Prevention (referred to in this section as the ‘CDC’)  
6 shall be headed by the Director of the Centers for Disease  
7 Control and Prevention (referred to in this section as the  
8 ‘Director’), who shall be appointed by the President, by  
9 and with the advice and consent of the Senate. Such indi-  
10 vidual shall also serve as the Administrator of the Agency  
11 for Toxic Substances and Disease Registry consistent with  
12 section 104(i) of the Comprehensive Environmental Re-  
13 sponse, Compensation, and Liability Act. The Director  
14 shall perform functions provided for in subsection (b) and  
15 such other functions as the Secretary may prescribe.

16 “(b) FUNCTIONS.—The Secretary, acting through the  
17 Director, shall—

18 “(1) implement and exercise applicable authori-  
19 ties and responsibilities provided for in this Act or  
20 other applicable law related to the investigation, de-  
21 tection, identification, prevention, or control of dis-  
22 eases or conditions to preserve and improve public  
23 health domestically and globally and address injuries  
24 and occupational and environmental hazards, as ap-  
25 propriate;



1           “(2) be responsible for the overall direction of  
2 the CDC and for the establishment and implementa-  
3 tion of policies related to the management and oper-  
4 ation of programs and activities within the CDC;

5           “(3) coordinate and oversee the operation of  
6 centers, institutes, and offices within the CDC;

7           “(4) support, in consultation with the heads of  
8 such centers, institutes, and offices, program coordi-  
9 nation across such centers, institutes, and offices, in-  
10 cluding through priority setting reviews and the de-  
11 velopment of strategic plans, to reduce unnecessary  
12 duplication and encourage collaboration between pro-  
13 grams;

14           “(5) oversee the development, implementation,  
15 and updating of the strategic plan established pursu-  
16 ant to subsection (c);

17           “(6) ensure that appropriate strategic planning,  
18 including the use of performance metrics, is con-  
19 ducted by such centers, institutes, and offices to fa-  
20 cilitate and improve CDC programs and activities;

21           “(7) communicate, including through convening  
22 annual meetings, with public and private entities re-  
23 garding relevant public health programs and activi-  
24 ties, and, as applicable, the strategic plan estab-  
25 lished pursuant to subsection (c).

1 “(c) STRATEGIC PLAN.—

2 “(1) IN GENERAL.—Not later than 1 year after  
3 the date of enactment of the PREVENT Pandemics  
4 Act, and at least every 4 years thereafter, the Direc-  
5 tor shall develop and submit to the Committee on  
6 Health, Education, Labor, and Pensions and the  
7 Committee on Appropriations of the Senate and the  
8 Committee on Energy and Commerce and the Com-  
9 mittee on Appropriations of the House of Represent-  
10 atives, and post on the website of the CDC, a coordi-  
11 nated strategy to provide strategic direction and fa-  
12 cilitate collaboration across the centers, institutes,  
13 and offices within the CDC. Such strategy shall be  
14 known as the ‘CDC Strategic Plan’.

15 “(2) REQUIREMENTS.—The CDC Strategic  
16 Plan shall—

17 “(A) identify strategic priorities and objec-  
18 tives related to—

19 “(i) preventing, reducing, and elimi-  
20 nating the spread of communicable and  
21 noncommunicable diseases or conditions,  
22 and addressing injuries, and occupational  
23 and environmental hazards;

24 “(ii) supporting the efforts of State,  
25 local, and Tribal health departments to

1 prevent and reduce the prevalence of the  
2 diseases or conditions under clause (i);

3 “(iii) containing, mitigating, and end-  
4 ing disease outbreaks;

5 “(iv) enhancing global and domestic  
6 public health capacity, capabilities, and  
7 preparedness, including public health data,  
8 surveillance, workforce, and laboratory ca-  
9 pacity and safety; and

10 “(v) other priorities, as established by  
11 the Director;

12 “(B) describe the capacity and capabilities  
13 necessary to achieve the priorities and objec-  
14 tives under subparagraph (A), and progress to-  
15 wards achieving such capacity and capabilities,  
16 as appropriate; and

17 “(C) include a description of how the CDC  
18 Strategic Plan incorporates—

19 “(i) strategic communications;

20 “(ii) partnerships with private sector  
21 entities, and State, local, and Tribal health  
22 departments, and other public sector enti-  
23 ties, as appropriate; and

24 “(iii) coordination with other agencies  
25 and offices of the Department of Health

1                   and Human Services and other Federal de-  
2                   partments and agencies, as appropriate.

3                   “(3) USE OF PLANS.—Strategic plans developed  
4                   and updated by the centers, institutes, and offices of  
5                   the CDC shall be prepared regularly and in such a  
6                   manner that such plans will be informed by the CDC  
7                   Strategic Plan developed and updated under this  
8                   subsection.

9                   “(d) APPEARANCES BEFORE CONGRESS.—

10                   “(1) IN GENERAL.—Each fiscal year, the Direc-  
11                   tor shall appear before the Committee on Health,  
12                   Education, Labor, and Pensions of the Senate and  
13                   the Committee on Energy and Commerce of the  
14                   House of Representatives at hearings on topics such  
15                   as—

16                   “(A) support for State, local, and Tribal  
17                   public health preparedness and responses to any  
18                   recent or ongoing public health emergency, in-  
19                   cluding—

20                   “(i) any objectives, activities, or initia-  
21                   tives that have been carried out, or are  
22                   planned, by the Director to prepare for, or  
23                   respond to, the public health emergency,  
24                   including relevant strategic communica-  
25                   tions or partnerships and any gaps or chal-

1           lenges identified in such objectives, activi-  
2           ties, or initiatives;

3           “(ii) any objectives and planned ac-  
4           tivities for the upcoming fiscal year to ad-  
5           dress gaps in, or otherwise improve, State,  
6           local, and Tribal public health prepared-  
7           ness; and

8           “(iii) other potential all-hazard  
9           threats that the Director is preparing to  
10          address;

11          “(B) activities related to public health and  
12          functions of the Director described in sub-  
13          section (b); and

14          “(C) updates on other relevant activities  
15          supported or conducted by the CDC, or in col-  
16          laboration or coordination with the heads of  
17          other Federal departments, agencies, or stake-  
18          holders, as appropriate.

19          “(2) CLARIFICATIONS.—

20          “(A) WAIVER AUTHORITY.—The Chair of  
21          the Committee on Health, Education, Labor,  
22          and Pensions of the Senate or the Chair of the  
23          Committee on Energy and Commerce of the  
24          House of Representatives may waive the re-  
25          quirements of paragraph (1) for the applicable

1 fiscal year with respect to the applicable Com-  
2 mittee.

3 “(B) SCOPE OF REQUIREMENTS.—The re-  
4 quirements of this subsection shall not be con-  
5 strued to impact the appearance of other Fed-  
6 eral officials or the Director at hearings of ei-  
7 ther Committee described in paragraph (1) at  
8 other times and for purposes other than the  
9 times and purposes described in paragraph (1).

10 “(3) CLOSED HEARINGS.—Information that is  
11 not appropriate for disclosure during an open hear-  
12 ing under paragraph (1) in order to protect national  
13 security may instead be discussed in a closed hear-  
14 ing that immediately follows the open hearing.”.

15 (b) APPLICATION.—The first sentence of section  
16 305(a) of the Public Health Service Act, as added by sub-  
17 section (a), shall not apply to the Director of the Centers  
18 for Disease Control and Prevention who is serving on the  
19 date of enactment of this Act.

20 **SEC. 103. ADDITIONAL PROVISIONS RELATED TO THE CEN-**  
21 **TERS FOR DISEASE CONTROL AND PREVEN-**  
22 **TION.**

23 Title III of the Public Health Service Act (42 U.S.C.  
24 241 et seq.) is amended by inserting after section 305,  
25 as added by section 102, the following:

1 **“SEC. 305A. ADDITIONAL PROVISIONS RELATED TO THE**  
2 **CENTERS FOR DISEASE CONTROL AND PRE-**  
3 **VENTION.**

4 “(a) APPOINTMENTS.—

5 “(1) IN GENERAL.—Unless otherwise specified  
6 in statute, the heads of the centers or institutes of  
7 the Centers for Disease Control and Prevention shall  
8 be appointed by the Secretary, acting through the  
9 Director of the Centers for Disease Control and Pre-  
10 vention (referred to in this section as the ‘Director’).  
11 Each such individual shall be appointed for 5 years.

12 “(2) REAPPOINTMENTS.—At the end of a 5-  
13 year term, an individual appointed under paragraph  
14 (1) shall be reappointed in accordance with stand-  
15 ards applicable to the relevant appointment mecha-  
16 nism and as determined by the Secretary, as appli-  
17 cable.

18 “(3) NO LIMIT ON TERMS.—There shall be no  
19 limit on the number of terms that any individual ap-  
20 pointed under this subsection may serve.

21 “(4) VACANCIES.—If the position of a head of  
22 a center or institute described in paragraph (1) be-  
23 comes vacant before the end of a term, the head of  
24 such center or institute appointed to fill the vacancy  
25 shall be appointed for a 5-year term starting on the  
26 date of such appointment.

1           “(5) CURRENT POSITIONS AND EXEMPTIONS.—

2                   “(A) IN GENERAL.—Each such individual  
3           who is serving on the date of enactment of the  
4           PREVENT Pandemics Act shall be deemed to  
5           be appointed for a 5-year term under this sub-  
6           section beginning on such date of enactment.

7                   “(B) EXEMPTIONS.—The Secretary may  
8           exempt the head of a center or institute from  
9           the 5-year term described in subparagraph (A)  
10          if such Secretary determines such exemption is  
11          necessary in order to hire or retain talented in-  
12          dividuals.

13                  “(6) RULE OF CONSTRUCTION.—Nothing in  
14          this subsection shall be construed to limit the au-  
15          thority of the Secretary or the Director to terminate  
16          the appointment of a head of a center or institute  
17          described in paragraph (1) before the expiration of  
18          such individual’s 5-year term.

19                  “(7) NATURE OF APPOINTMENT.—Appoint-  
20          ments and reappointments under this subsection  
21          shall be made on the basis of ability and experience  
22          as it relates to the mission of the Centers for Dis-  
23          ease Control and Prevention and its components, in-  
24          cluding compliance with relevant legal requirements.

25                  “(b) OTHER TRANSACTIONS.—



1           “(1) IN GENERAL.—In carrying out activities of  
2 the Centers for Disease Control and Prevention, the  
3 Director may enter into transactions other than a  
4 contract, grant, or cooperative agreement for pur-  
5 poses of biosurveillance, infectious disease modeling,  
6 and public health preparedness and response, includ-  
7 ing related research.

8           “(2) WRITTEN DETERMINATION.—With respect  
9 to a project that is expected to cost the Centers for  
10 Disease Control and Prevention more than  
11 \$5,000,000, the Director may exercise the authority  
12 under paragraph (1) only upon a written determina-  
13 tion by the Assistant Secretary for Financial Re-  
14 sources of the Department of Health and Human  
15 Services, that the use of such authority is essential  
16 to promoting the success of the project. The author-  
17 ity of the Assistant Secretary for Financial Re-  
18 sources under this paragraph may not be delegated.

19           “(3) GUIDELINES.—The Director, in consulta-  
20 tion with the Secretary, shall establish guidelines re-  
21 garding the use of the authority under paragraph  
22 (1). Such guidelines shall include auditing require-  
23 ments.”.

1 **SEC. 104. PUBLIC HEALTH AND MEDICAL PREPAREDNESS**  
2 **AND RESPONSE COORDINATION.**

3 (a) PUBLIC HEALTH EMERGENCY FUND.—Section  
4 319(b) of the Public Health Service Act (42 U.S.C.  
5 247d(b)) is amended—

6 (1) in paragraph (2)—

7 (A) in subparagraph (E), by striking  
8 “and” at the end;

9 (B) by redesignating subparagraph (F) as  
10 subparagraph (G); and

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

13 “(F) support the initial deployment and  
14 distribution of contents of the Strategic Na-  
15 tional Stockpile, as appropriate; and”; and

16 (2) by amending paragraph (3)(A) to read as  
17 follows:

18 “(A) the expenditures made from the Pub-  
19 lic Health Emergency Fund in such fiscal year,  
20 including—

21 “(i) the amount obligated;

22 “(ii) the recipient or recipients of such  
23 obligated funds;

24 “(iii) the specific response activities  
25 such obligated funds will support; and

1                   “(iv) the declared or potential public  
2                   health emergency for which such funds  
3                   were obligated; and”.

4           (b) IMPROVING PUBLIC HEALTH AND MEDICAL PRE-  
5 PAREDNESS AND RESPONSE COORDINATION.—

6           (1) COORDINATION WITH FEDERAL AGEN-  
7 CIES.—Section 2801 of the Public Health Service  
8 Act (42 U.S.C. 300hh) is amended by adding at the  
9 end the following:

10          “(c) COORDINATION WITH FEDERAL AGENCIES.—In  
11 leading the Federal public health and medical response to  
12 a declared or potential public health emergency, consistent  
13 with this section, the Secretary shall coordinate with, and  
14 may request support from, other Federal departments and  
15 agencies, as appropriate in order to carry out necessary  
16 activities and leverage the expertise of such departments  
17 and agencies, which may include the provision of assist-  
18 ance at the direction of the Secretary related to supporting  
19 the public health and medical response for States, local-  
20 ities, and Tribes.”.

21           (2) ASPR DUTIES.—Section 2811(b) of the  
22 Public Health Service Act (42 U.S.C. 300hh–10(b))  
23 is amended—

24                   (A) in paragraph (1), by inserting “and,  
25                   consistent with the National Response Frame-

1 work and other applicable provisions of law, as-  
2 sist the Secretary in carrying out the functions  
3 under section 2801” before the period; and

4 (B) in paragraph (4)—

5 (i) in subparagraph (E) by striking  
6 “the actions necessary to overcome these  
7 obstacles.” and inserting “recommend ac-  
8 tions necessary to overcome these obsta-  
9 cles, such as—

10 “(i) improving coordination with rel-  
11 evant Federal officials;

12 “(ii) partnering with other public or  
13 private entities to leverage capabilities  
14 maintained by such entities, as appropriate  
15 and consistent with this subsection; and

16 “(iii) coordinating efforts to support  
17 or establish new capabilities, as appro-  
18 priate.”; and

19 (ii) in subparagraph (G)—

20 (I) by redesignating clauses (i)  
21 and (ii) as subclauses (I) and (II) and  
22 adjusting the margins accordingly;

23 (II) in the matter preceding sub-  
24 clause (I), as so redesignated—

1 (aa) by inserting “each year,  
2 including national-level and  
3 State-level full-scale exercises not  
4 less than once every 5 years”  
5 after “operational exercises”; and

6 (bb) by striking “exercises  
7 based on—” and inserting “exer-  
8 cises—

9 “(i) based on”;

10 (III) by striking the period and  
11 inserting a semicolon; and

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

14 “(ii) that assess the ability of the  
15 Strategic National Stockpile, as appro-  
16 priate, to provide medical countermeasures,  
17 medical products, and other supplies, in-  
18 cluding ancillary medical supplies, to sup-  
19 port the response to a public health emer-  
20 gency or potential public health emergency,  
21 including a threat that requires the large-  
22 scale and simultaneous deployment of  
23 stockpiles and a long-term public health  
24 and medical response; and

1                   “(iii) conducted in coordination with  
2                   State and local health officials.”.

3           (c) APPEARANCES BEFORE AND REPORTS TO CON-  
4 GRESS.—Section 2811 of the Public Health Service Act  
5 (42 U.S.C. 300hh–10) is amended by adding at the end  
6 the following:

7           “(g) APPEARANCES BEFORE CONGRESS.—

8                   “(1) IN GENERAL.—Each fiscal year, the As-  
9                   sistant Secretary for Preparedness and Response  
10                   shall appear before the Committee on Health, Edu-  
11                   cation, Labor, and Pensions of the Senate and the  
12                   Committee on Energy and Commerce of the House  
13                   of Representatives at hearings, on topics such as—

14                           “(A) coordination of Federal activities to  
15                           prepare for, and respond to, public health emer-  
16                           gencies;

17                           “(B) activities and capabilities of the Stra-  
18                           tegic National Stockpile, including whether, and  
19                           the degree to which, recommendations made  
20                           pursuant to section 2811–1(c)(1)(A) have been  
21                           met;

22                           “(C) support for State, local, and Tribal  
23                           public health and medical preparedness;

1           “(D) activities implementing the counter-  
2 measures budget plan described under sub-  
3 section (b)(7), including—

4                   “(i) any challenges in meeting the full  
5 range of identified medical countermeasure  
6 needs; and

7                   “(ii) progress in supporting advanced  
8 research, development, and procurement of  
9 medical countermeasures, pursuant to sub-  
10 section (b)(3);

11           “(E) the strategic direction of, and activi-  
12 ties related to, the sustainment of manufac-  
13 turing surge capacity and capabilities for med-  
14 ical countermeasures pursuant to section 319L  
15 and the distribution and deployment of such  
16 countermeasures;

17           “(F) any additional objectives, activities,  
18 or initiatives that have been carried out or are  
19 planned by the Assistant Secretary for Pre-  
20 paredness and Response and associated chal-  
21 lenges, as appropriate;

22           “(G) the specific all-hazards threats that  
23 the Assistant Secretary for Preparedness and  
24 Response is preparing to address, or that are

1 being addressed, through the activities de-  
2 scribed in subparagraphs (A) through (F); and

3 “(H) objectives, activities, or initiatives re-  
4 lated to the coordination and consultation re-  
5 quired under subsections (b)(4)(H) and  
6 (b)(4)(I), in a manner consistent with para-  
7 graph (3), as appropriate.

8 “(2) CLARIFICATIONS.—

9 “(A) WAIVER AUTHORITY.—The Chair of  
10 the Committee on Health, Education, Labor,  
11 and Pensions of the Senate or the Chair of the  
12 Committee on Energy and Commerce of the  
13 House of Representatives may waive the re-  
14 quirements of paragraph (1) for the applicable  
15 fiscal year with respect to the applicable Com-  
16 mittee.

17 “(B) SCOPE OF REQUIREMENTS.—The re-  
18 quirements of this subsection shall not be con-  
19 strued to impact the appearance of other Fed-  
20 eral officials or the Assistant Secretary at hear-  
21 ings of either Committee described in para-  
22 graph (1) at other times and for purposes other  
23 than the times and purposes described in para-  
24 graph (1).



1           “(3) CLOSED HEARINGS.—Information that is  
2           not appropriate for disclosure during an open hear-  
3           ing under paragraph (1) in order to protect national  
4           security may instead be discussed in a closed hear-  
5           ing that immediately follows such open hearing.”.

6           (d) ANNUAL REPORT ON EMERGENCY RESPONSE  
7           AND PREPAREDNESS.—Section 2801 of the Public Health  
8           Service Act (42 U.S.C. 300hh), as amended by subsection  
9           (b), is further amended by adding at the end the following:

10          “(d) ANNUAL REPORT ON EMERGENCY RESPONSE  
11          AND PREPAREDNESS.—The Secretary shall submit a writ-  
12          ten report each fiscal year to the Committee on Health,  
13          Education, Labor, and Pensions of the Senate and the  
14          Committee on Energy and Commerce of the House of  
15          Representatives, containing—

16                 “(1) updated information related to an assess-  
17                 ment of the response to any public health emergency  
18                 declared, or otherwise in effect, during the previous  
19                 fiscal year;

20                 “(2) findings related to drills and operational  
21                 exercises completed in the previous fiscal year pursu-  
22                 ant to section 2811(b)(4)(G);

23                 “(3) the state of public health preparedness and  
24                 response capabilities for chemical, biological, radio-

1 logical, and nuclear threats, including emerging in-  
2 fectious diseases; and

3 “(4) any challenges in preparing for or respond-  
4 ing to such threats, as appropriate.”.

5 (e) GAO REPORT ON INTERAGENCY AGREEMENTS  
6 AND COORDINATION.—Not later than 3 years after the  
7 date of enactment of this Act, the Comptroller General  
8 of the United States shall—

9 (1) conduct a review of previous and current  
10 interagency agreements established between the Sec-  
11 retary of Health and Human Services and the heads  
12 of other relevant Federal departments or agencies  
13 pursuant to section 2801(b) of the Public Health  
14 Service Act (42 U.S.C. 300hh(b)), including—

15 (A) the specific roles and responsibilities of  
16 each Federal department or agency that is a  
17 party to any such interagency agreement;

18 (B) the manner in which specific capabili-  
19 ties of each such Federal department or agency  
20 may be utilized under such interagency agree-  
21 ments;

22 (C) the frequency with which such inter-  
23 agency agreements have been utilized;

24 (D) gaps, if any, in interagency agree-  
25 ments that prevent the Secretary from carrying

1 out the goals under section 2802 of the Public  
2 Health Service Act (42 U.S.C. 300hh–1);

3 (E) barriers, if any, to establishing or uti-  
4 lizing such interagency agreements; and

5 (F) recommendations, if any, on the ways  
6 in which such interagency agreements can be  
7 improved to address the gaps and barriers iden-  
8 tified under subparagraphs (D) and (E);

9 (2) conduct a review of the implementation and  
10 utilization of the authorities described under section  
11 2801(e) of the Public Health Service Act (42 U.S.C.  
12 300hh(e)); and

13 (3) submit to the Committee on Health, Edu-  
14 cation, Labor, and Pensions of the Senate and the  
15 Committee on Energy and Commerce of the House  
16 of Representatives a report on the reviews under  
17 paragraphs (1) and (2), including related rec-  
18 ommendations, as applicable.

19 **SEC. 105. STRENGTHENING PUBLIC HEALTH COMMUNICA-**  
20 **TION.**

21 Subsection (b) of section 319F of the Public Health  
22 Service Act (42 U.S.C. 247d–6) is amended to read as  
23 follows:

24 “(b) PUBLIC HEALTH INFORMATION AND COMMU-  
25 NICATIONS ADVISORY COMMITTEE.—

1           “(1) IN GENERAL.—The Secretary shall estab-  
2           lish an advisory committee to be known as the Pub-  
3           lic Health Information and Communications Advi-  
4           sory Committee (referred to in this subsection as the  
5           ‘Advisory Committee’).

6           “(2) DUTIES.—The Advisory Committee shall  
7           make recommendations to the Secretary and report  
8           on—

9                   “(A) critical aspects of communication and  
10                  dissemination of scientific and evidence-based  
11                  public health information during public health  
12                  emergencies, including—

13                           “(i) the role and impact of misin-  
14                           formation on the response to such public  
15                           health emergencies;

16                           “(ii) the role of risk communication  
17                           before and during such public health emer-  
18                           gencies; and

19                           “(iii) other relevant factors, as the  
20                           Secretary determines appropriate;

21                   “(B) information from academic institu-  
22                   tions, community-based organizations, and  
23                   other nongovernmental organizations related to  
24                   evidence-based or evidence-informed strategies

1 and best practices to effectively communicate  
2 and disseminate such information;

3 “(C) strategies to improve communication  
4 and dissemination of scientific and evidence-  
5 based public health information to the public, to  
6 improve such communication between Federal,  
7 State, local, and Tribal health officials, and, as  
8 appropriate, to address misinformation during  
9 public health emergencies, including strategies  
10 to—

11 “(i) identify the most effective meth-  
12 ods for the dissemination of information  
13 during a public health emergency, with  
14 consideration of the needs of at-risk popu-  
15 lations;

16 “(ii) determine best practices and  
17 communicate information to populations  
18 that may be impacted by such misinforma-  
19 tion; and

20 “(iii) adapt approaches for the dis-  
21 semination of information, as appropriate,  
22 to address emerging trends related to mis-  
23 information.

24 “(3) COMPOSITION.—The Advisory Committee  
25 shall be composed of—

1           “(A) appropriate Federal officials, ap-  
2           pointed by the Secretary, who shall serve as  
3           nonvoting members; and

4           “(B) individuals, appointed by the Sec-  
5           retary, with expertise in public health (including  
6           individuals with experience in State, local, and  
7           Tribal health departments), medicine, commu-  
8           nications, related technology, psychology, men-  
9           tal health and substance use disorders, national  
10          security, and other areas, as the Secretary de-  
11          termines appropriate, who shall serve as voting  
12          members.

13          “(4) DISSEMINATION.—The Secretary shall re-  
14          view the recommendations of the Advisory Com-  
15          mittee and, not later than 180 days after receipt of  
16          the report under paragraph (2), shall submit to the  
17          Committee on Health, Education, Labor, and Pen-  
18          sions of the Senate and the Committee on Energy  
19          and Commerce of the House of Representatives a re-  
20          port describing any actions planned by the Secretary  
21          related to the communication and dissemination of  
22          scientific and evidence-based public health informa-  
23          tion, including addressing misinformation, as appro-  
24          priate.

1           “(5) TERMINATION.—The Advisory Committee  
2           shall terminate 4 years after the date of enactment  
3           of the PREVENT Pandemics Act.”.

4 **SEC. 106. OFFICE OF PANDEMIC PREPAREDNESS AND RE-**  
5 **SPONSE POLICY.**

6           (a) IN GENERAL.—There is established in the Execu-  
7           tive Office of the President an Office of Pandemic Pre-  
8           paredness and Response Policy (referred to in this section  
9           as the “Office”), which shall be headed by a Director (re-  
10          ferred to in this section as the “Director”) appointed by  
11          the President and who shall be compensated at the rate  
12          provided for level II of the Executive Schedule in section  
13          5313 of title 5, United States Code. The President is au-  
14          thorized to appoint not more than 2 Associate Directors,  
15          who shall be compensated at a rate not to exceed that pro-  
16          vided for level III of the Executive Schedule in section  
17          5314 of such title. Associate Directors shall perform such  
18          functions as the Director may prescribe.

19          (b) FUNCTIONS OF THE DIRECTOR.—The primary  
20          function of the Director is to provide advice, within the  
21          Executive Office of the President, on pandemic prepared-  
22          ness and response policy, and support strategic coordina-  
23          tion and communication with respect to relevant activities  
24          across the Federal Government. In addition to such other  
25          functions and activities as the President may assign, the

1 Director, consistent with applicable laws and the National  
2 Response Framework, shall—

3 (1) serve as the principal advisor to the Presi-  
4 dent on all matters related to pandemic prepared-  
5 ness and response policy and make recommendations  
6 to the President regarding pandemic and other bio-  
7 logical threats that may impact national security;

8 (2) coordinate Federal activities to prepare for,  
9 and respond to, pandemic and other biological  
10 threats, by—

11 (A) providing strategic direction to the  
12 heads of applicable Federal departments, agen-  
13 cies, and offices, including—

14 (i) the establishment, implementation,  
15 prioritization, and assessment of policy  
16 goals and objectives across the Executive  
17 Office of the President and such depart-  
18 ments, agencies, and offices;

19 (ii) supporting the assessment and  
20 clarification of roles and responsibilities re-  
21 lated to such Federal activities; and

22 (iii) supporting the development and  
23 implementation of metrics and perform-  
24 ance measures to evaluate the extent to



1           which applicable activities meet such goals  
2           and objectives;

3           (B) providing, in consultation with the  
4           Secretary of Health and Human Services and  
5           the heads of other relevant Federal depart-  
6           ments, agencies, and offices, leadership with re-  
7           spect to the National Biodefense Strategy and  
8           related activities pursuant to section 1086 of  
9           the National Defense Authorization Act for Fis-  
10          cal Year 2017 (6 U.S.C. 104) and section 363  
11          of the William M. (Mac) Thornberry National  
12          Defense Authorization Act for Fiscal Year 2021  
13          (6 U.S.C. 105);

14          (C) facilitating coordination and commu-  
15          nication between such Federal departments,  
16          agencies, and offices to improve preparedness  
17          for, and response to, such threats;

18          (D) ensuring that the authorities, capabili-  
19          ties, and expertise of each such department,  
20          agency, and office are appropriately leveraged  
21          to facilitate the whole-of-Government response  
22          to such threats;

23          (E) overseeing coordination of Federal ef-  
24          forts to prepare for and support the production,  
25          supply, and distribution of relevant medical

1 products and supplies during a response to a  
2 pandemic or other biological threat, as applica-  
3 ble and appropriate, including supporting Fed-  
4 eral efforts to assess any relevant vulnerabilities  
5 in the supply chain of such products and sup-  
6 plies;

7 (F) overseeing coordination of Federal ef-  
8 forts for the basic and advanced research, de-  
9 velopment, manufacture, and procurement of  
10 medical countermeasures, including by—

11 (i) serving, with the Secretary of  
12 Health and Human Services, as co-Chair  
13 of the Public Health Emergency Medical  
14 Countermeasures Enterprise established  
15 pursuant to section 2811–1 of the Public  
16 Health Service Act (42 U.S.C. 300hh–  
17 10a); and

18 (ii) promoting coordination between  
19 the medical countermeasure research, de-  
20 velopment, and procurement activities of  
21 respective Federal departments and agen-  
22 cies, including to advance the discovery  
23 and development of new medical products  
24 and technologies;

1 (G) convening heads of Federal depart-  
2 ments and agencies, as appropriate, on topics  
3 related to capabilities to prepare for, and re-  
4 spond to, such threats;

5 (H) assessing and advising on inter-  
6 national cooperation in preparing for, and re-  
7 sponding to, such threats to advance the na-  
8 tional security objectives of the United States;  
9 and

10 (I) overseeing other Federal activities to  
11 assess preparedness for, and responses to, such  
12 threats, including—

13 (i) drills and operational exercises  
14 conducted pursuant to applicable provi-  
15 sions of law; and

16 (ii) Federal after-action reports devel-  
17 oped following such drills and exercises or  
18 a response to a pandemic or other biologi-  
19 cal threat;

20 (3) promote and support the development of  
21 relevant expertise and capabilities within the Federal  
22 Government to ensure that the United States can  
23 quickly detect, identify, and respond to such threats,  
24 and provide recommendations, as appropriate, to the  
25 President;

1           (4) consult with the Director of the Office of  
2           Management and Budget and other relevant officials  
3           within the Executive Office of the President, includ-  
4           ing the Assistant to the President for National Secu-  
5           rity Affairs and the Director of the Office of Science  
6           and Technology Policy, regarding activities related  
7           to preparing for, and responding to, such threats  
8           and relevant research and emerging technologies  
9           that may advance the biosecurity and preparedness  
10          and response goals of the Federal Government;

11          (5) identify opportunities to leverage current  
12          and emerging technologies, including through public-  
13          private partnerships, as appropriate, to address such  
14          threats and advance the preparedness and response  
15          goals of the Federal Government; and

16          (6) ensure that findings of Federal after-action  
17          reports conducted pursuant to paragraph (2)(I)(ii)  
18          are implemented to the maximum extent feasible  
19          within the Federal Government.

20          (c) SUPPORT FROM OTHER AGENCIES.—Each de-  
21          partment, agency, and instrumentality of the executive  
22          branch of the Federal Government, including any inde-  
23          pendent agency, is authorized to support the Director by  
24          providing the Director such information as the Director

1 determines necessary to carry out the functions of the Di-  
2 rector under this section.

3 (d) PREPAREDNESS OUTLOOK REPORT.—

4 (1) IN GENERAL.—Within its first year of oper-  
5 ation, the Director, in consultation with the heads of  
6 relevant Federal departments and agencies and  
7 other officials within the Executive Office of the  
8 President, shall through a report submitted to the  
9 President and made available to the public, to the  
10 extent practicable, identify and describe situations  
11 and conditions which warrant special attention with-  
12 in the next 5 years, involving current and emerging  
13 problems of national significance related to pan-  
14 demic or other biological threats, and opportunities  
15 for, and the barriers to, the research, development,  
16 and procurement of medical countermeasures to ade-  
17 quately respond to such threats.

18 (2) REVISIONS.—The Office shall revise the re-  
19 port under paragraph (1) not less than once every  
20 5 years and work with relevant Federal officials to  
21 address the problems, barriers, opportunities, and  
22 actions identified under this report through the de-  
23 velopment of the President's Budgets and programs.

24 (e) INTERDEPARTMENTAL WORKING GROUP.—The  
25 Director shall lead an interdepartmental working group

1 that will meet on a regular basis to evaluate national bio-  
2 security and pandemic preparedness issues and make rec-  
3 ommendations to the heads of applicable Federal depart-  
4 ments, agencies and offices. The working group shall con-  
5 sist of representatives from—

6 (1) the Office of Pandemic Preparedness and  
7 Response Policy, to serve as the chair;

8 (2) the Department of Health and Human  
9 Services;

10 (3) the Department of Homeland Security;

11 (4) the Department of Defense;

12 (5) the Office of Management and Budget; and

13 (6) other Federal Departments and agencies.

14 (f) ADDITIONAL FUNCTIONS OF THE DIRECTOR.—

15 The Director, in addition to the other duties and functions  
16 set forth in this section—

17 (1) shall—

18 (A) serve as a member of the Domestic  
19 Policy Council and the National Security Coun-  
20 cil;

21 (B) serve as a member of the Intergovern-  
22 mental Science, Engineering, and Technology  
23 Advisory Panel under section 205(b) of the Na-  
24 tional Science and Technology Policy, Organiza-  
25 tion, and Priorities Act of 1976 (42 U.S.C.

1           6614(b)) and the Federal Coordinating Council  
2           for Science, Engineering and Technology under  
3           section 401 of such Act (42 U.S.C. 6651);

4           (C) consult with State, Tribal, local, and  
5           territorial governments, industry, academia,  
6           professional societies, and other stakeholders,  
7           as appropriate;

8           (D) use for administrative purposes, on a  
9           reimbursable basis, the available services, equip-  
10          ment, personnel, and facilities of Federal, State,  
11          and local agencies; and

12          (E) at the President's request, perform  
13          such other duties and functions and enter into  
14          contracts and other arrangements for studies,  
15          analyses, and related services with public or pri-  
16          vate entities, as applicable and appropriate; and

17          (2) may hold such hearings in various parts of  
18          the United States as necessary to determine the  
19          views of the entities and individuals referred to in  
20          paragraph (1) and of the general public, concerning  
21          national needs and trends in pandemic preparedness  
22          and response.

23          (g) STAFFING AND DETAILEES.—In carrying out  
24          functions under this section, the Director may—

1           (1) appoint not more than 25 individuals to  
2           serve as employees of the Office as necessary to  
3           carry out this section;

4           (2) fix the compensation of such personnel at a  
5           rate to be determined by the Director, up to the  
6           amount of annual compensation (excluding expenses)  
7           specified in section 102 of title 3, United States  
8           Code;

9           (3) utilize the services of consultants, which  
10          may include by obtaining services described under  
11          section 3109(b) of title 5, United States Code, at  
12          rates not to exceed the rate of basic pay for level IV  
13          of the Executive Schedule; and

14          (4) direct, with the concurrence of the Sec-  
15          retary of a department or head of an agency, the  
16          temporary reassignment within the Federal Govern-  
17          ment of personnel employed by such department or  
18          agency, in order to carry out the functions of the Of-  
19          fice.

20          (h) PREPAREDNESS REVIEW AND REPORT.—The Di-  
21          rector, in consultation with the heads of applicable Federal  
22          departments, agencies, and offices, shall—

23                 (1) not later than 1 year after the date of en-  
24                 actment of this Act, conduct a review of applicable  
25                 Federal strategies, policies, procedures, and after-ac-



1       tion reports to identify gaps and inefficiencies re-  
2       lated to pandemic preparedness and response;

3           (2) not later than 18 months after the date of  
4       enactment of this Act, and every 2 years thereafter,  
5       submit to the President and the Committee on  
6       Health, Education, Labor, and Pensions of the Sen-  
7       ate and the Committee on Energy and Commerce of  
8       the House of Representatives a report describing—

9           (A) current and emerging pandemic and  
10       other biological threats that pose a significant  
11       level of risk to national security;

12          (B) the roles and responsibilities of the  
13       Federal Government in preparing for, and re-  
14       sponding to, such threats;

15          (C) the findings of the review conducted  
16       under paragraph (1);

17          (D) any barriers or limitations related to  
18       addressing such findings;

19          (E) current and planned activities to up-  
20       date Federal strategies, policies, and procedures  
21       to address such findings, consistent with appli-  
22       cable laws and the National Response Frame-  
23       work;

24          (F) current and planned activities to sup-  
25       port the development of expertise within the

1 Federal Government pursuant to subsection  
2 (b)(3); and

3 (G) opportunities to improve Federal pre-  
4 paredness and response capacities and capabili-  
5 ties through the use of current and emerging  
6 technologies.

7 (i) NONDUPLICATION OF EFFORT.—The Director  
8 shall ensure that activities carried out under this section  
9 do not unnecessarily duplicate the efforts of other Federal  
10 departments, agencies, and offices.

11 (j) CONFORMING AMENDMENTS.—

12 (1) Section 2811–1 of the Public Health Serv-  
13 ice Act (42 U.S.C. 300hh–10a) is amended—

14 (A) in the second sentence of subsection  
15 (a), by striking “shall serve as chair” and in-  
16 serting “and the Director of the Office of Pan-  
17 demic Preparedness and Response Policy shall  
18 serve as co-chairs”; and

19 (B) in subsection (b)—

20 (i) by redesignating paragraph (10) as  
21 paragraph (11); and

22 (ii) by inserting after paragraph (9)  
23 the following:

24 “(10) The Director of the Office of Pandemic  
25 Preparedness and Response Policy.”.

1           (2) Section 101(c)(1) of the National Security  
2 Act of 1947 (50 U.S.C. 3021(c)(1)) is amended by  
3 inserting “the Director of the Office of Pandemic  
4 Preparedness and Response Policy” after “Treas-  
5 ury,”.

6           (3) The National Science and Technology Pol-  
7 icy, Organization, and Priorities Act of 1976 (42  
8 U.S.C. 6601 et seq.) is amended—

9           (A) in section 205(b)(2) (42 U.S.C.  
10 6614(b)(2))—

11           (i) by striking “and (C)” and insert-  
12 ing “(C)”; and

13           (ii) by striking the period at the end  
14 and inserting “; and (D) the Director of  
15 the Office of Pandemic Preparedness and  
16 Response Policy.”; and

17           (B) in section 401(b) (42 U.S.C. 6651(b)),  
18 by inserting “, the Director of the Office of  
19 Pandemic Preparedness and Response Policy,”  
20 after “Technology Policy”.

1                   **Subtitle B—State and Local**  
2                   **Readiness**

3 **SEC. 111. IMPROVING STATE AND LOCAL PUBLIC HEALTH**  
4                   **SECURITY.**

5           (a) IN GENERAL.—Section 319C–1(b)(2) of the Pub-  
6 lic Health Service Act (42 U.S.C. 247d–3a(b)(2)) is  
7 amended—

8           (1) in subparagraph (A)—

9                   (A) in clause (vii), by inserting “during  
10 and” before “following a public health emer-  
11 gency”;

12                   (B) by amending clause (viii) to read as  
13 follows:

14                           “(viii) a description of how the entity,  
15 as applicable and appropriate, will coordi-  
16 nate with State emergency preparedness  
17 and response plans in public health emer-  
18 gency preparedness, including State edu-  
19 cation agencies (as defined in section 8101  
20 of the Elementary and Secondary Edu-  
21 cation Act of 1965), State child care lead  
22 agencies (designated under section 658D  
23 of the Child Care and Development Block  
24 Grant Act of 1990), and other relevant  
25 State agencies”;

1 (C) in clause (xi), by striking “; and” and  
2 inserting a semicolon;

3 (D) by redesignating clause (xii) as clause  
4 (xiii); and

5 (E) by inserting after clause (xi) the fol-  
6 lowing:

7 “(xii) a description of how the entity  
8 will provide technical assistance to improve  
9 public health preparedness and response,  
10 as appropriate, to agencies or other enti-  
11 ties that operate facilities within the enti-  
12 ty’s jurisdiction in which there is an in-  
13 creased risk of infectious disease outbreaks  
14 in the event of a public health emergency  
15 declared under section 319, such as resi-  
16 dential care facilities, group homes, and  
17 other similar settings; and”;

18 (2) by redesignating subparagraphs (D)  
19 through (H) as subparagraphs (E) through (I), re-  
20 spectively; and

21 (3) by inserting after subparagraph (C) the fol-  
22 lowing:

23 “(D) an assurance that the entity will re-  
24 quire relevant staff to complete relevant pre-  
25 paredness and response trainings, including

1 trainings related to efficient and effective oper-  
2 ation during an incident or event within an In-  
3 cident Command System;”.

4 (b) APPLICABILITY.—The amendments made by sub-  
5 section (a) shall not apply with respect to any cooperative  
6 agreement entered into prior to the date of enactment of  
7 this Act.

8 **SEC. 112. SUPPORTING ACCESS TO MENTAL HEALTH AND**  
9 **SUBSTANCE USE DISORDER SERVICES DUR-**  
10 **ING PUBLIC HEALTH EMERGENCIES.**

11 (a) AUTHORITIES.—Section 501(d) of the Public  
12 Health Service Act (42 U.S.C. 290aa(d)) is amended—

13 (1) by redesignating paragraphs (24) and (25)  
14 as paragraphs (25) and (26), respectively; and

15 (2) by inserting after paragraph (23) the fol-  
16 lowing:

17 “(24) support the continued access to, or avail-  
18 ability of, mental health and substance use disorder  
19 services during, or in response to, a public health  
20 emergency declared under section 319, including in  
21 consultation with, as appropriate, the Assistant Sec-  
22 retary for Preparedness and Response and the heads  
23 of other relevant agencies, in preparing for, and re-  
24 sponding to, a public health emergency;”.

1 (b) STRATEGIC PLAN.—Section 501(l)(4) of the Pub-  
2 lic Health Service Act (42 U.S.C. 290aa(l)(4)) is amend-  
3 ed—

4 (1) in subparagraph (E), by striking “and” at  
5 the end;

6 (2) in subparagraph (F), by striking the period  
7 and inserting “; and”; and

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

9 “(G) specify a strategy to support the con-  
10 tinued access to, or availability of, mental  
11 health and substance use disorder services, in-  
12 cluding to at-risk individuals (as defined in sec-  
13 tion 2802(b)(4)), during, or in response to,  
14 public health emergencies declared pursuant to  
15 section 319.”.

16 (c) BIENNIAL REPORT CONCERNING ACTIVITIES AND  
17 PROGRESS.—Section 501(m) of the Public Health Service  
18 Act (42 U.S.C. 290aa(m)) is amended—

19 (1) by redesignating paragraphs (4) through  
20 (7) as paragraphs (5) through (8), respectively;

21 (2) by inserting after paragraph (3) the fol-  
22 lowing:

23 “(4) a description of the Administration’s ac-  
24 tivities to support the continued provision of mental  
25 health and substance use disorder services, as appli-

1 cable, in response to public health emergencies de-  
2 clared pursuant to section 319;” and

3 (3) in paragraph (5), as so redesignated—

4 (A) by redesignating subparagraphs (D)  
5 and (E) as subparagraphs (E) and (F), respec-  
6 tively; and

7 (B) by inserting after subparagraph (C)  
8 the following:

9 “(D) relevant preparedness and response  
10 activities;”.

11 (d) ADVISORY COUNCILS.—Not later than 1 year  
12 after the date of enactment of this Act, the Assistant Sec-  
13 retary for Mental Health and Substance Use shall issue  
14 a report to the Committee on Health, Education, Labor,  
15 and Pensions of the Senate and the Committee on Energy  
16 and Commerce of the House of Representatives, reflecting  
17 the feedback of the advisory councils for the Center for  
18 Substance Abuse Treatment, the Center for Substance  
19 Abuse Prevention, and the Center for Mental Health Serv-  
20 ices, pursuant to section 502 of the Public Health Service  
21 Act (42 U.S.C. 290aa–1), with recommendations to im-  
22 prove the continued provision of mental health and sub-  
23 stance use disorder services during a public health emer-  
24 gency declared under section 319 of such Act (42 U.S.C.  
25 247d), and the provision of such services as part of the



1 public health and medical response to such an emergency,  
2 consistent with title XXVIII of such Act (42 U.S.C. 300hh  
3 et seq.), including related to the capacity of the mental  
4 health and substance use disorder workforce and flexibili-  
5 ties provided to awardees of mental health and substance  
6 use disorder programs.

7 (e) GAO REPORT.—Not later than 3 years after the  
8 date of enactment of this Act, the Comptroller General  
9 of the United States shall submit to the Committee on  
10 Health, Education, Labor, and Pensions of the Senate and  
11 the Committee on Energy and Commerce of the House  
12 of Representatives a report on programs and activities of  
13 the Substance Abuse and Mental Health Services Admin-  
14 istration to support the provision of mental health and  
15 substance use disorder services and related activities dur-  
16 ing the COVID–19 pandemic, including the provision of  
17 such services as part of the medical and public health re-  
18 sponse to such pandemic. Such report shall—

19 (1) examine the role played by the advisory  
20 councils described in section 502 of the Public  
21 Health Service Act (42 U.S.C. 290aa–1) and the  
22 National Mental Health and Substance Use Policy  
23 Laboratory established under section 501A of such  
24 Act (42 U.S.C. 290aa–0) in providing technical as-  
25 sistance and recommendations to the Substance

1 Abuse and Mental Health Services Administration to  
2 support the response of such agency to the public  
3 health emergency declared under section 319 of the  
4 Public Health Service Act (42 U.S.C. 247d) with re-  
5 spect to COVID-19;

6 (2) describe the manner in which existing  
7 awardees of mental health and substance use dis-  
8 order programs provided and altered delivery of  
9 services during such public health emergency, includ-  
10 ing information on the populations served by such  
11 awardees and any barriers faced in delivering serv-  
12 ices; and

13 (3) describe activities of the Substance Abuse  
14 and Mental Health Services Administration to sup-  
15 port the response to such public health emergency,  
16 including through technical assistance, provision of  
17 services, and any flexibilities provided to such exist-  
18 ing awardees, and any barriers faced in imple-  
19 menting such activities.

20 **SEC. 113. TRAUMA CARE REAUTHORIZATION.**

21 (a) IN GENERAL.—Section 1201 of the Public Health  
22 Service Act (42 U.S.C. 300d) is amended—

23 (1) in subsection (a)—

24 (A) in paragraph (3)—

1 (i) by inserting “analyze,” after “com-  
2 pile,”; and

3 (ii) by inserting “and medically under-  
4 served areas” before the semicolon;

5 (B) in paragraph (4), by adding “and”  
6 after the semicolon;

7 (C) by striking paragraph (5); and

8 (D) by redesignating paragraph (6) as  
9 paragraph (5);

10 (2) by redesignating subsection (b) as sub-  
11 section (c); and

12 (3) by inserting after subsection (a) the fol-  
13 lowing:

14 “(b) TRAUMA CARE READINESS AND COORDINA-  
15 TION.—The Secretary, acting through the Assistant Sec-  
16 retary for Preparedness and Response, shall support the  
17 efforts of States and consortia of States to coordinate and  
18 improve emergency medical services and trauma care dur-  
19 ing a public health emergency declared by the Secretary  
20 pursuant to section 319 or a major disaster or emergency  
21 declared by the President under section 401 or 501, re-  
22 spectively, of the Robert T. Stafford Disaster Relief and  
23 Emergency Assistance Act. Such support may include—

24 “(1) developing, issuing, and updating guid-  
25 ance, as appropriate, to support the coordinated

1 medical triage and evacuation to appropriate medical  
2 institutions based on patient medical need, taking  
3 into account regionalized systems of care;

4 “(2) disseminating, as appropriate, information  
5 on evidence-based or evidence-informed trauma care  
6 practices, taking into consideration emergency med-  
7 ical services and trauma care systems, including  
8 such practices identified through activities conducted  
9 under subsection (a) and which may include the  
10 identification and dissemination of performance  
11 metrics, as applicable and appropriate; and

12 “(3) other activities, as appropriate, to optimize  
13 a coordinated and flexible approach to the emer-  
14 gency response and medical surge capacity of hos-  
15 pitals, other health care facilities, critical care, and  
16 emergency medical systems.”.

17 (b) GRANTS TO IMPROVE TRAUMA CARE IN RURAL  
18 AREAS.—Section 1202 of the Public Health Service Act  
19 (42 U.S.C. 300d–3) is amended—

20 (1) by amending the section heading to read as  
21 follows: “**GRANTS TO IMPROVE TRAUMA CARE**  
22 **IN RURAL AREAS**”;

23 (2) by amending subsections (a) and (b) to read  
24 as follows:

1       “(a) IN GENERAL.—The Secretary shall award  
2 grants to eligible entities for the purpose of carrying out  
3 research and demonstration projects to support the im-  
4 provement of emergency medical services and trauma care  
5 in rural areas through the development of innovative uses  
6 of technology, training and education, transportation of  
7 seriously injured patients for the purposes of receiving  
8 such emergency medical services, access to prehospital  
9 care, evaluation of protocols for the purposes of improve-  
10 ment of outcomes and dissemination of any related best  
11 practices, activities to facilitate clinical research, as appli-  
12 cable and appropriate, and increasing communication and  
13 coordination with applicable State or Tribal trauma sys-  
14 tems.

15       “(b) ELIGIBLE ENTITIES.—

16               “(1) IN GENERAL.—To be eligible to receive a  
17 grant under this section, an entity shall be a public  
18 or private entity that provides trauma care in a  
19 rural area.

20               “(2) PRIORITY.—In awarding grants under this  
21 section, the Secretary shall give priority to eligible  
22 entities that will provide services under the grant in  
23 any rural area identified by a State under section  
24 1214(d)(1).”; and

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

1       “(d) REPORTS.—An entity that receives a grant  
2 under this section shall submit to the Secretary such re-  
3 ports as the Secretary may require to inform administra-  
4 tion of the program under this section.”.

5       (e) PILOT GRANTS FOR TRAUMA CENTERS.—Section  
6 1204 of the Public Health Service Act (42 U.S.C. 300d-  
7 6) is amended—

8           (1) by amending the section heading to read as  
9 follows: “**PILOT GRANTS FOR TRAUMA CEN-**  
10 **TERS**”;

11          (2) in subsection (a)—

12           (A) by striking “not fewer than 4” and in-  
13 serting “10”;

14           (B) by striking “that design, implement,  
15 and evaluate” and inserting “to design, imple-  
16 ment, and evaluate new or existing”;

17           (C) by striking “emergency care” and in-  
18 serting “emergency medical”; and

19           (D) by inserting “, and improve access to  
20 trauma care within such systems” before the  
21 period;

22          (3) in subsection (b)(1), by striking subpara-  
23 graphs (A) and (B) and inserting the following:

24           “(A) a State or consortia of States;

1           “(B) an Indian Tribe or Tribal organiza-  
2           tion (as defined in section 4 of the Indian Self-  
3           Determination and Education Assistance Act);

4           “(C) a consortium of level I, II, or III  
5           trauma centers designated by applicable State  
6           or local agencies within an applicable State or  
7           region, and, as applicable, other emergency  
8           services providers; or

9           “(D) a consortium or partnership of non-  
10          profit Indian Health Service, Indian Tribal, and  
11          urban Indian trauma centers.”;

12          (4) in subsection (c)—

13                (A) in the matter preceding paragraph  
14                (1)—

15                   (i) by striking “that proposes a pilot  
16                   project”;

17                   (ii) by striking “an emergency medical  
18                   and trauma system that—” and inserting  
19                   “a new or existing emergency medical and  
20                   trauma system. Such eligible entity shall  
21                   use amounts awarded under this sub-  
22                   section to carry out 2 or more of the fol-  
23                   lowing activities.”;

24                (B) in paragraph (1) —

1 (i) by striking “coordinates” and in-  
2 serting “Strengthening coordination and  
3 communication”; and

4 (ii) by striking “an approach to emer-  
5 gency medical and trauma system access  
6 throughout the region, including 9–1–1  
7 Public Safety Answering Points and emer-  
8 gency medical dispatch;” and inserting  
9 “approaches to improve situational aware-  
10 ness and emergency medical and trauma  
11 system access, including distribution of pa-  
12 tients during a mass casualty incident,  
13 throughout the region.”;

14 (C) in paragraph (2)—

15 (i) by striking “includes” and insert-  
16 ing “Providing”;

17 (ii) by inserting “support patient  
18 movement to” after “region to”; and

19 (iii) by striking the semicolon and in-  
20 serting a period;

21 (D) in paragraph (3)—

22 (i) by striking “allows for” and insert-  
23 ing “Improving”; and

24 (ii) by striking “; and” and inserting  
25 a period;



1 (E) in paragraph (4), by striking “includes  
2 a consistent” and inserting “Supporting a con-  
3 sistent”; and

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

5 “(5) Establishing, implementing, and dissemi-  
6 nating, or utilizing existing, as applicable, evidence-  
7 based or evidence-informed practices across facilities  
8 within such emergency medical and trauma system  
9 to improve health outcomes, including such practices  
10 related to management of injuries, and the ability of  
11 such facilities to surge.

12 “(6) Conducting activities to facilitate clinical  
13 research, as applicable and appropriate.”;

14 (5) in subsection (d)(2)—

15 (A) in subparagraph (A)—

16 (i) in the matter preceding clause (i),  
17 by striking “the proposed” and inserting  
18 “the applicable emergency medical and  
19 trauma system”;

20 (ii) in clause (i), by inserting “or  
21 Tribal entity” after “equivalent State of-  
22 fice”; and

23 (iii) in clause (vi), by striking “; and”  
24 and inserting a semicolon;

1 (B) by redesignating subparagraph (B) as  
2 subparagraph (C); and

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

5 “(B) for eligible entities described in sub-  
6 paragraph (C) or (D) of subsection (b)(1), a de-  
7 scription of, and evidence of, coordination with  
8 the applicable State Office of Emergency Med-  
9 ical Services (or equivalent State Office) or ap-  
10 plicable such office for a Tribe or Tribal organi-  
11 zation; and”;

12 (6) in subsection (e)—

13 (A) in paragraph (1), by striking “\$1 for  
14 each \$3” and inserting “\$1 for each \$5”; and

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

16 “(3) WAIVER.—The Secretary may waive all or  
17 part of the matching requirement described in para-  
18 graph (1) for any fiscal year for a State, consortia  
19 of States, Indian Tribe or Tribal organization, or  
20 trauma center, if the Secretary determines that ap-  
21 plying such matching requirement would result in  
22 serious hardship or an inability to carry out the pur-  
23 poses of the pilot program.”;

1           (7) in subsection (f), by striking “population in  
2           a medically underserved area” and inserting “medi-  
3           cally underserved population”;

4           (8) in subsection (g)—

5                 (A) in the matter preceding paragraph (1),  
6                 by striking “described in”;

7                 (B) in paragraph (2), by striking “the sys-  
8                 tem characteristics that contribute to” and in-  
9                 serting “opportunities for improvement, includ-  
10                ing recommendations for how to improve”;

11                (C) by striking paragraph (4);

12                (D) by redesignating paragraphs (5) and  
13                (6) as paragraphs (4) and (5), respectively;

14                (E) in paragraph (4), as so redesignated,  
15                by striking “; and” and inserting a semicolon;

16                (F) in paragraph (5), as so redesignated,  
17                by striking the period and inserting “; and”;

18                and

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

20                “(6) any evidence-based or evidence-informed  
21                strategies developed or utilized pursuant to sub-  
22                section (c)(5).”; and

23                (9) by amending subsection (h) to read as fol-  
24                lows:

1       “(h) DISSEMINATION OF FINDINGS.—Not later than  
2 1 year after the completion of the final project under sub-  
3 section (a), the Secretary shall submit to the Committee  
4 on Health, Education, Labor, and Pensions of the Senate  
5 and the Committee on Energy and Commerce of the  
6 House of Representatives a report describing the informa-  
7 tion contained in each report submitted pursuant to sub-  
8 section (g) and any additional actions planned by the Sec-  
9 retary related to regionalized emergency care and trauma  
10 systems.”.

11       (d) PROGRAM FUNDING.—Section 1232(a) of the  
12 Public Health Service Act (42 U.S.C. 300d–32(a)) is  
13 amended by striking “2010 through 2014” and inserting  
14 “2023 through 2027”.

15 **SEC. 114. ASSESSMENT OF CONTAINMENT AND MITIGATION**  
16 **OF INFECTIOUS DISEASES.**

17       (a) GAO STUDY.—The Comptroller General of the  
18 United States shall conduct a study that reviews a geo-  
19 graphically diverse sample of States and territories that,  
20 in response to the COVID–19 pandemic, implemented pre-  
21 paredness and response plans that included isolation and  
22 quarantine recommendations or requirements. Such study  
23 shall include—

24               (1) a review of such State and territorial pre-  
25               paredness and response plans in place during the

1 COVID–19 pandemic, an assessment of the extent  
2 to which such plans facilitated or presented chal-  
3 lenges to State and territorial responses to such  
4 public health emergency, including response activi-  
5 ties relating to isolation and quarantine to prevent  
6 the spread of COVID–19; and

7 (2) a description of the technical assistance pro-  
8 vided by the Federal Government to help States and  
9 territories facilitate such response activities during  
10 responses to relevant public health emergencies de-  
11 clared by the Secretary of Health and Human Serv-  
12 ices pursuant to section 319 of the Public Health  
13 Service Act, including the public health emergency  
14 with respect to COVID–19, and a review of the de-  
15 gree to which such State and territorial plans were  
16 implemented and subsequently revised in response to  
17 the COVID–19 pandemic to address any challenges.

18 (b) REPORT.—Not later than 18 months after the  
19 date of enactment of this Act, the Comptroller General  
20 of the United States shall submit a report on the study  
21 under subsection (a) to the Committee on Health, Edu-  
22 cation, Labor, and Pensions of the Senate and the Com-  
23 mittee on Energy and Commerce of the House of Rep-  
24 resentatives.

1 **TITLE II—IMPROVING PUBLIC**  
2 **HEALTH PREPAREDNESS AND**  
3 **RESPONSE CAPACITY**

4 **Subtitle A—Addressing Disparities**  
5 **and Improving Public Health**  
6 **Emergency Responses**

7 **SEC. 201. ADDRESSING SOCIAL DETERMINANTS OF HEALTH**  
8 **AND IMPROVING HEALTH OUTCOMES.**

9 (a) IN GENERAL.—Part B of title III of the Public  
10 Health Service Act (42 U.S.C. 243 et seq.) is amended—

11 (1) by inserting after section 317U the fol-  
12 lowing:

13 **“SEC. 317V. ADDRESSING SOCIAL DETERMINANTS OF**  
14 **HEALTH AND IMPROVING HEALTH OUT-**  
15 **COMES.**

16 “(a) IN GENERAL.—The Secretary shall, as appro-  
17 priate, award grants, contracts, or cooperative agreements  
18 to eligible entities for the conduct of evidence-based or evi-  
19 dence-informed projects, which may include the develop-  
20 ment of networks to improve health outcomes and reduce  
21 health disparities by improving the capacity of such enti-  
22 ties to address social determinants of health in commu-  
23 nities.

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

1           “(1)(A) be a State, local, or Tribal health de-  
2           partment, community-based organization, Indian  
3           Tribe or Tribal organization (as such terms are de-  
4           fined in section 4 of the Indian Self-Determination  
5           and Education Assistance Act), urban Indian orga-  
6           nization (as defined in section 4 of the Indian  
7           Health Care Improvement Act), or other public or  
8           private entity, as the Secretary determines appro-  
9           priate; or

10           “(B) be a consortia or public-private partner-  
11           ship of entities described in subparagraph (A);

12           “(2) submit to the Secretary an application at  
13           such time, in such manner, and containing such in-  
14           formation as the Secretary shall require;

15           “(3) in the case of an entity other than a com-  
16           munity-based organization, demonstrate a history of  
17           successfully working with an established community-  
18           based organization to address health disparities;

19           “(4) submit a plan to conduct activities de-  
20           scribed in subsection (a) based on a community  
21           needs assessment that takes into account community  
22           input; and

23           “(5) demonstrate the capacity to effectively im-  
24           plement evidence-based or evidence-informed strate-  
25           gies to address health disparities among underserved

1 populations, which may include rural, racial, and  
2 ethnic minority populations and people with disabili-  
3 ties, in a timely manner.

4 “(c) USE OF FUNDS.—An entity described in sub-  
5 section (b) shall use funds received under subsection (a),  
6 in consultation with State, local, and Tribal health depart-  
7 ments, community-based organizations, and other entities  
8 with experience addressing social determinants of health  
9 or reducing health disparities, as applicable, for one or  
10 more of the following purposes:

11 “(1) Supporting the implementation, evaluation,  
12 and dissemination of strategies, including culturally-  
13 appropriate strategies, to address social deter-  
14 minants of health, based on the identified needs of  
15 the community that is the subject of the assessment  
16 submitted under subsection (b)(4), through evidence-  
17 informed or evidence-based programs and through  
18 the support and use of public health and health care  
19 professionals to address such social determinants of  
20 health.

21 “(2) Establishing, maintaining, or improving, in  
22 consultation with State, local, or Tribal health de-  
23 partments, technology platforms or networks to sup-  
24 port coordination among appropriate entities, and  
25 providing information on health and related social



1 services, which may include activities to improve  
2 data collection for public health purposes, in a man-  
3 ner that is consistent with applicable Federal and  
4 State privacy law.

5 “(3) Implementing best practices for improving  
6 health outcomes and reducing disease among under-  
7 served populations, including rural or racial and eth-  
8 nic minority populations.

9 “(4) Supporting consideration of social deter-  
10 minants of health in preparing for, and responding  
11 to, public health emergencies, through outreach,  
12 education, research, and other relevant activities.

13 “(d) BEST PRACTICES AND TECHNICAL ASSIST-  
14 ANCE.—The Secretary, in consultation with the Director  
15 of the Office of Minority Health, may award grants, con-  
16 tracts, and cooperative agreements to public or nonprofit  
17 private entities, including minority serving institutions  
18 (defined, for purposes of this subsection, as institutions  
19 and programs described in section 326(e)(1) of the Higher  
20 Education Act of 1965 and institutions described in sec-  
21 tion 371(a) of such Act of 1965), to—

22 “(1) identify or facilitate the development of  
23 best practices to support improved health outcomes  
24 and reduce health disparities by addressing social  
25 determinants of health;

1           “(2) provide technical assistance, training, and  
2           evaluation assistance to award recipients under sub-  
3           section (a);

4           “(3) disseminate best practices, including to  
5           award recipients under subsection (a); and

6           “(4) establish or operate regional centers to de-  
7           velop, evaluate, and disseminate effective strategies  
8           on the utilization of preventive health care services  
9           to address social determinants of health, including  
10          supporting research and training related to such  
11          strategies.

12          “(e) AWARD PERIODS.—The Secretary shall issue  
13          awards under this section for periods of not more than  
14          5 years and may issue extensions of such award periods  
15          for an additional period of up to 3 years.

16          “(f) REPORT.—Not later than September 30, 2026,  
17          the Secretary shall submit to the Committee on Health,  
18          Education, Labor, and Pensions of the Senate and the  
19          Committee on Energy and Commerce of the House of  
20          Representatives a report that includes information on ac-  
21          tivities funded under this section. Such report shall in-  
22          clude a description of—

23                 “(1) changes in the capacity of public health  
24                 entities to address social determinants of health in  
25                 communities, including any applicable platforms or

1 networks developed or utilized to coordinate health  
2 and related social services and any changes in work-  
3 force capacity or capabilities;

4 “(2) improvements in health outcomes and in  
5 reducing health disparities in medically underserved  
6 communities;

7 “(3) activities conducted to support consider-  
8 ation of social determinants of health in preparing  
9 for, and responding to, public health emergencies,  
10 through outreach, education, and other relevant ac-  
11 tivities;

12 “(4) communities and populations served by re-  
13 cipients of awards under subsection (a);

14 “(5) activities supported under subsection (e);  
15 and

16 “(6) other relevant activities and outcomes, as  
17 determined by the Secretary.

18 “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
19 carry out this section, there are authorized to be appro-  
20 priated \$70,000,000 for each of fiscal years 2023 through  
21 2027.”; and

22 (2) by striking section 330D (42 U.S.C. 254c-  
23 4).

24 (b) GAO STUDY AND REPORT.—Not later than 4  
25 years after the date of enactment of this Act, the Comp-

1 troller General of the United States shall submit to the  
2 Committee on Health, Education, Labor, and Pensions of  
3 the Senate and the Energy and Commerce Committee on Energy and  
4 Commerce of the House of Representatives a report on  
5 the program authorized under section 317V of the Public  
6 Health Service Act, as added by subsection (a), including  
7 a review of the outcomes and effectiveness of the program  
8 and coordination with other programs in the Department  
9 of Health and Human Services with similar goals to en-  
10 sure that there was no unnecessary duplication of efforts.

11 **SEC. 202. NATIONAL ACADEMIES OF SCIENCES, ENGINEER-**  
12 **ING, AND MEDICINE REPORT.**

13 (a) IN GENERAL.—Not later than 45 days after the  
14 date of enactment of this Act, the Secretary of Health and  
15 Human Services shall seek to enter into a contract with  
16 the National Academies of Sciences, Engineering, and  
17 Medicine (referred to in this section as the “National  
18 Academies”) to conduct a study to examine health dispari-  
19 ties and the effect of such disparities on health outcomes,  
20 which may include health outcomes related to pandemic  
21 and other public health emergencies.

22 (b) REPORT.—Pursuant to the contract under sub-  
23 section (a), the National Academies shall, not later than  
24 3 years after the date of enactment of this Act, issue a

1 report informed by the study conducted under such sub-  
2 section that includes—

3           (1) consideration of previous recommendations  
4           made by the National Academies related to health  
5           disparities, including in the report titled “Unequal  
6           Treatment: Confronting Racial and Ethnic Dispari-  
7           ties in Healthcare”;

8           (2) recommendations for strategies to improve  
9           health outcomes by reducing health disparities,  
10          which may include education and training; and

11          (3) an assessment of ongoing research and  
12          strategies to reduce health disparities and improve  
13          health outcomes, including effective service delivery  
14          models.

15          (c) CLARIFICATION.—In completing the requirements  
16 of the contract under this section, the National Academies  
17 may leverage relevant ongoing work of the National Acad-  
18 emies, including ongoing work related to the impact of  
19 Federal policies on health disparities.

20          (d) AUTHORIZATION OF APPROPRIATIONS.—There is  
21 authorized to be appropriated \$2,000,000 for fiscal year  
22 2023 to carry out this section.

1           **Subtitle B—Improving Public**  
2           **Health Data**

3   **SEC. 211. MODERNIZING BIOSURVEILLANCE CAPABILITIES**  
4                   **AND INFECTIOUS DISEASE DATA COLLEC-**  
5                   **TION.**

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

8                   (1) in subsection (b)(1)(A), by striking “, and  
9           local” and inserting “, local, and Tribal”;

10                   (2) in subsection (c)—

11                           (A) in paragraph (1), by inserting “mod-  
12                           ernize,” after “establish,”;

13                           (B) in paragraph (3)(B), by inserting “,  
14                           and make recommendations to improve the  
15                           quality of data collected pursuant to subpara-  
16                           graph (A) to ensure complete, accurate, and  
17                           timely sharing of such data, as appropriate,  
18                           across such elements as described in subpara-  
19                           graph (A)” after “under subparagraph (A)”;

20                           (C) in paragraph (5)—

21                                   (i) in subparagraph (A)—

22   (I) in the matter preceding clause  
23                                   (i), by striking “and operating” and  
24                                   inserting “, operating, and updating,  
25                                   as appropriate,”;

1 (II) in clause (iv), by striking  
2 “and” at the end;

3 (III) in clause (v), by striking the  
4 period and inserting “; and”; and

5 (IV) by adding at the end the fol-  
6 lowing:

7 “(vi) in collaboration with State, local,  
8 and Tribal public health officials, integrate  
9 and update applicable existing public  
10 health data systems and networks of the  
11 Department of Health and Human Serv-  
12 ices to reflect technological advancements,  
13 consistent with section 2823, as applica-  
14 ble.”; and

15 (ii) in subparagraph (B)—

16 (I) in clause (i), by inserting  
17 “and 180 days after the date of enact-  
18 ment of the PREVENT Pandemics  
19 Act,” after “Innovation Act of  
20 2019.”;

21 (II) in clause (ii), by inserting  
22 “experts in privacy and data secu-  
23 rity;” after “forecasting);”; and

24 (III) in clause (iii)—

1 (aa) in subclause (V), by  
2 striking “and” at the end;

3 (bb) in subclause (VI), by  
4 striking the period and inserting  
5 a semicolon; and

6 (cc) by adding at the end  
7 the following:

8 “(VII) strategies to integrate lab-  
9 oratory and public health data sys-  
10 tems and capabilities to support rapid  
11 and accurate reporting of laboratory  
12 test results and associated relevant  
13 data;

14 “(VIII) strategies to improve the  
15 collection and reporting of relevant,  
16 aggregated, deidentified demographic  
17 data to inform responses to public  
18 health emergencies, including identi-  
19 fication of at-risk populations and to  
20 address potential health disparities;  
21 and

22 “(IX) strategies to improve the  
23 electronic exchange of health informa-  
24 tion between State and local health  
25 departments and health care providers



1 and facilities to improve public health  
2 surveillance.”; and

3 (D) in paragraph (6)(A)—

4 (i) in the matter preceding clause (i),  
5 by inserting “and every 5 years there-  
6 after,” after “Innovation Act of 2019,”

7 (ii) in clause (iii)—

8 (I) in subclause (III), by striking  
9 “and” at the end; and

10 (II) by adding at the end the fol-  
11 lowing:

12 “(V) improve coordination and  
13 collaboration, as appropriate, with  
14 other Federal departments; and

15 “(VI) implement applicable les-  
16 sons learned from recent public health  
17 emergencies to address gaps in situa-  
18 tional awareness and biosurveillance  
19 capabilities;”;

20 (iii) in clause (iv), by striking “and”  
21 at the end;

22 (iv) in clause (v), by striking the pe-  
23 riod and inserting “, including a descrip-  
24 tion of how such steps will further the

1 goals of the network, consistent with para-  
2 graph (1); and”;

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

4 “(vi) identifies and demonstrates  
5 measurable steps the Secretary will take to  
6 further develop and integrate infectious  
7 disease detection, support rapid and accu-  
8 rate reporting of laboratory test results  
9 during a public health emergency, and im-  
10 prove coordination and collaboration with  
11 State, local, and Tribal public health offi-  
12 cials, clinical laboratories, and other enti-  
13 ties with expertise in public health surveil-  
14 lance.”;

15 (3) in subsection (d)—

16 (A) in paragraph (1), by inserting “, act-  
17 ing through the Director of the Centers for Dis-  
18 ease Control and Prevention and in coordina-  
19 tion with the heads of other appropriate agen-  
20 cies and offices within the Department of  
21 Health and Human Services,” after “the Sec-  
22 retary”;

23 (B) in paragraph (2)(C), by inserting “,  
24 including any public-private partnerships or

1 other partnerships entered into to improve such  
2 capacity” before the semicolon; and

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

4 “(6) NON-DUPLICATION OF EFFORT.—The Sec-  
5 retary shall ensure that activities carried out under  
6 an award under this subsection do not unnecessarily  
7 duplicate efforts of other agencies and offices within  
8 the Department of Health and Human Services.”;

9 (4) by amending subsection (i) to read as fol-  
10 lows:

11 “(i) AUTHORIZATION OF APPROPRIATIONS.—There  
12 are authorized to be appropriated—

13 “(1) to carry out subsection (a), \$25,000,000  
14 for each of fiscal years 2022 and 2023; and

15 “(2) to carry out subsections (b), (c), and (d),  
16 \$136,800,000 for each of fiscal years 2022 and  
17 2023.”; and

18 (5) by striking “tribal” each place it appears  
19 and inserting “Tribal”.

20 **SEC. 212. GENOMIC SEQUENCING, ANALYTICS, AND PUBLIC**  
21 **HEALTH SURVEILLANCE OF PATHOGENS.**

22 (a) GUIDANCE SUPPORTING GENOMIC SEQUENCING  
23 OF PATHOGENS COLLABORATION.—The Secretary of  
24 Health and Human Services (referred to in this section  
25 as the “Secretary”), in consultation with the heads of

1 other Federal departments or agencies, as appropriate,  
2 shall issue guidance to support collaboration relating to  
3 genomic sequencing of pathogens, including the use of new  
4 and innovative approaches and technology for the detec-  
5 tion, characterization, and sequencing of pathogens, to im-  
6 prove public health surveillance and preparedness and re-  
7 sponse activities, consistent with section 2824 of the Pub-  
8 lic Health Service Act, as added by subsection (b). Such  
9 guidance shall address the secure sharing, for public  
10 health surveillance purposes, of specimens of such patho-  
11 gens, between appropriate entities and public health au-  
12 thorities, consistent with the regulations promulgated  
13 under section 264(c) of the Health Insurance Portability  
14 and Accountability Act of 1996 (42 U.S.C. 1320d–2 note),  
15 as applicable, and in a manner that protects personal pri-  
16 vacy to the extent required by applicable privacy law, at  
17 a minimum, and the appropriate use of sequence data de-  
18 rived from such specimens.

19 (b) GENOMIC SEQUENCING PROGRAM.—Title  
20 XXVIII of the Public Health Service Act (42 U.S.C.  
21 300hh et seq.) is amended by adding at the end the fol-  
22 lowing

1 **“SEC. 2824. GENOMIC SEQUENCING, ANALYTICS, AND PUB-**  
2 **LIC HEALTH SURVEILLANCE OF PATHOGENS**  
3 **PROGRAM.**

4 “(a) GENOMIC SEQUENCING, ANALYTICS, AND PUB-  
5 LIC HEALTH SURVEILLANCE OF PATHOGENS PRO-  
6 GRAM.—The Secretary, acting through the Director of the  
7 Centers for Disease Control and Prevention and in con-  
8 sultation with the Director of the National Institutes of  
9 Health and heads of other departments and agencies, as  
10 appropriate, shall strengthen and expand activities related  
11 to genomic sequencing of pathogens, including new and  
12 innovative approaches and technology for the detection,  
13 characterization, and sequencing of pathogens, analytics,  
14 and public health surveillance, including—

15 “(1) continuing and expanding activities, which  
16 may include existing genomic sequencing activities  
17 related to advanced molecular detection, to—

18 “(A) identify and respond to emerging in-  
19 fectious disease threats; and

20 “(B) identify the potential use of genomic  
21 sequencing technologies, advanced computing,  
22 and other advanced technology to inform sur-  
23 veillance activities and incorporate the use of  
24 such technologies, as appropriate, into related  
25 activities;

1           “(2) providing technical assistance and guid-  
2           ance to State, Tribal, local, and territorial public  
3           health departments to increase the capacity of such  
4           departments to perform genomic sequencing of  
5           pathogens, including recipients of funding under sec-  
6           tion 2821;

7           “(3) carrying out activities to enhance the capa-  
8           bilities of the public health workforce with respect to  
9           pathogen genomics, epidemiology, and  
10          bioinformatics, including through training; and

11          “(4) continuing and expanding activities, as ap-  
12          plicable, with public and private entities, including  
13          relevant departments and agencies, laboratories, aca-  
14          demic institutions, and industry.

15          “(b) PARTNERSHIPS.—For the purposes of carrying  
16          out the activities described in subsection (a), the Sec-  
17          retary, acting through the Director of the Centers for Dis-  
18          ease Control and Prevention, may award grants, contracts,  
19          or cooperative agreements to entities, including academic  
20          and other laboratories, with expertise in genomic sequenc-  
21          ing for public health purposes, including new and innova-  
22          tive approaches to, and related technology for, the detec-  
23          tion, characterization, and sequencing of pathogens.

24          “(c) CENTERS OF EXCELLENCE.—

1           “(1) IN GENERAL.—The Secretary shall, as ap-  
2           propriate, award grants, contracts, or cooperative  
3           agreements to public health agencies for the estab-  
4           lishment or operation of centers of excellence to pro-  
5           mote innovation in pathogen genomics and molecular  
6           epidemiology to improve the control of and response  
7           to pathogens that may cause a public health emer-  
8           gency. Such centers shall, as appropriate—

9                   “(A) identify and evaluate the use of  
10                  genomics, or other related technologies that  
11                  may advance public health preparedness and re-  
12                  sponse;

13                  “(B) improve the identification, develop-  
14                  ment, and use of tools for integrating and ana-  
15                  lyzing genomic and epidemiologic data;

16                  “(C) assist with genomic surveillance of,  
17                  and response to, infectious diseases, including  
18                  analysis of pathogen genomic data;

19                  “(D) conduct applied research to improve  
20                  public health surveillance of, and response to,  
21                  infectious diseases through innovation in patho-  
22                  gen genomics and molecular epidemiology; and

23                  “(E) develop and provide training mate-  
24                  rials for experts in the fields of genomics,

1 microbiology, bioinformatics, epidemiology, and  
2 other fields, as appropriate.

3 “(2) REQUIREMENTS.—To be eligible for an  
4 award under paragraph (1), an entity shall submit  
5 to the Secretary an application containing such in-  
6 formation as the Secretary may require, including a  
7 description of how the entity will partner, as applica-  
8 ble, with academic institutions or a consortium of  
9 academic partners that have relevant expertise, such  
10 as microbial genomics, molecular epidemiology, or  
11 the application of bioinformatics or statistics.

12 “(d) AUTHORIZATION.—For purposes of carrying out  
13 this section, there are authorized to be appropriated  
14 \$175,000,000 for each of fiscal years 2023 through  
15 2027.”.

16 **SEC. 213. SUPPORTING PUBLIC HEALTH DATA AVAIL-**  
17 **ABILITY AND ACCESS.**

18 (a) DESIGNATION OF PUBLIC HEALTH DATA STAND-  
19 ARDS.—Section 2823(a)(2) of the Public Health Service  
20 Act (42 U.S.C. 300hh–33(a)(2)) is amended—

21 (1) by striking “In carrying out” and inserting  
22 the following:

23 “(A) IN GENERAL.—In carrying out”; and

24 (2) by striking “shall, as appropriate and” and  
25 inserting “shall, not later than 2 years after the date



1 of enactment of the PREVENT Pandemics Act,”;  
2 and

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

4 “(B) SELECTION OF DATA AND TECH-  
5 NOLOGY STANDARDS.—The standards des-  
6 ignated as described in subparagraph (A) may  
7 include standards to improve—

8 “(i) the exchange of electronic health  
9 information for—

10 “(I) electronic case reporting;

11 “(II) syndromic surveillance;

12 “(III) reporting of vital statistics;

13 and

14 “(IV) reporting test orders and  
15 results electronically, including from  
16 laboratories;

17 “(ii) automated electronic reporting to  
18 relevant public health data systems of the  
19 Centers for Disease Control and Preven-  
20 tion; and

21 “(iii) such other use cases as the Sec-  
22 retary determines appropriate.

23 “(C) NO DUPLICATIVE EFFORTS.—

24 “(i) IN GENERAL.—In carrying out  
25 the requirements of this paragraph, the

1 Secretary, in consultation with the Office  
2 of the National Coordinator for Health In-  
3 formation Technology, may use input gath-  
4 ered (including input and recommendations  
5 gathered from the Health Information  
6 Technology Advisory Committee), and ma-  
7 terials developed, prior to the date of en-  
8 actment of the PREVENT Pandemics Act.

9 “(ii) PREVIOUSLY ADOPTED STAND-  
10 ARDS.—The data and technology standards  
11 designated pursuant to this paragraph may  
12 include the adoption of standards pre-  
13 viously adopted by the Secretary pursuant  
14 to section 3004.

15 “(D) PRIVACY AND SECURITY.—Nothing  
16 in this paragraph shall be construed as modi-  
17 fying applicable Federal or State information  
18 privacy or security law.”.

19 (b) STUDY ON LABORATORY INFORMATION STAND-  
20 ARDS.—

21 (1) IN GENERAL.—Not later than 1 year after  
22 the date of enactment of this Act, the Office of the  
23 National Coordinator for Health Information Tech-  
24 nology shall conduct a study to review the use of

1 standards for electronic ordering and reporting of  
2 laboratory test results.

3 (2) AREAS OF CONCENTRATION.—In conducting  
4 the study under paragraph (1), the Office of the Na-  
5 tional Coordinator for Health Information Tech-  
6 nology shall—

7 (A) determine the extent to which clinical  
8 laboratories are using standards for electronic  
9 ordering and reporting of laboratory test re-  
10 sults;

11 (B) assess trends in laboratory compliance  
12 with standards for ordering and reporting lab-  
13 oratory test results and the effect of such  
14 trends on the interoperability of laboratory data  
15 with public health data systems;

16 (C) identify challenges related to collection  
17 and reporting of demographic and other data  
18 elements with respect to laboratory test results;

19 (D) identify any challenges associated with  
20 using or complying with standards and report-  
21 ing laboratory test results with data elements  
22 identified in standards for electronic ordering  
23 and reporting of such results; and

1           (E) review other relevant areas determined  
2           appropriate by the Office of the National Coor-  
3           dinator for Health Information Technology.

4           (3) REPORT.—Not later than 2 years after the  
5           date of enactment of this Act, the Office of the Na-  
6           tional Coordinator for Health Information Tech-  
7           nology shall submit to the Committee on Health,  
8           Education, Labor, and Pensions of the Senate and  
9           the Committee on Energy and Commerce of the  
10          House of Representatives a report concerning the  
11          findings of the study conducted under paragraph  
12          (1).

13          (c) SUPPORTING INFORMATION SHARING THROUGH  
14          DATA USE AGREEMENTS.—

15                 (1) INTERAGENCY DATA USE AGREEMENTS  
16                 WITHIN THE DEPARTMENT OF HEALTH AND HUMAN  
17                 SERVICES FOR PUBLIC HEALTH EMERGENCIES.—

18                         (A) IN GENERAL.—The Secretary of  
19                         Health and Human Services (referred to in this  
20                         subsection as the “Secretary”) shall, as appro-  
21                         priate, facilitate the development of, or updates  
22                         to, memoranda of understanding, data use  
23                         agreements, or other applicable interagency  
24                         agreements regarding appropriate access, ex-  
25                         change, and use of public health data between

1 the Centers for Disease Control and Prevention,  
2 the Office of the Assistant Secretary for Pre-  
3 paredness and Response, other relevant agen-  
4 cies or offices within the Department of Health  
5 and Human Services, and other relevant Fed-  
6 eral agencies, in order to prepare for, identify,  
7 monitor, and respond to declared or potential  
8 public health emergencies.

9 (B) REQUIREMENTS.—In carrying out ac-  
10 tivities pursuant to subparagraph (A), the Sec-  
11 retary shall—

12 (i) ensure that the agreements and  
13 memoranda of understanding described in  
14 such subparagraph—

15 (I) address the methods of grant-  
16 ing access to data held by one agency  
17 or office with another to support the  
18 respective missions of such agencies  
19 or offices;

20 (II) consider minimum necessary  
21 principles of data sharing for appro-  
22 priate use;

23 (III) include appropriate privacy  
24 and cybersecurity protections; and

1 (IV) are subject to regular up-  
2 dates, as appropriate;

3 (ii) collaborate with the Centers for  
4 Disease Control and Prevention, the Office  
5 of the Assistant Secretary for Prepared-  
6 ness and Response, the Office of the Chief  
7 Information Officer, and, as appropriate,  
8 the Office of the National Coordinator for  
9 Health Information Technology, and other  
10 entities within the Department of Health  
11 and Human Services; and

12 (iii) consider the terms and conditions  
13 of any existing data use agreements with  
14 other public or private entities and any  
15 need for updates to such existing agree-  
16 ments, consistent with paragraph (2).

17 (2) DATA USE AGREEMENTS WITH EXTERNAL  
18 ENTITIES.—The Secretary, acting through the Di-  
19 rector of the Centers for Disease Control and Pre-  
20 vention and the Assistant Secretary for Prepared-  
21 ness and Response, may update memoranda of un-  
22 derstanding, data use agreements, or other applica-  
23 ble agreements and contracts to improve appropriate  
24 access, exchange, and use of public health data be-  
25 tween the Centers for Disease Control and Preven-

1 tion and the Office of the Assistant Secretary for  
2 Preparedness and Response and external entities, in-  
3 cluding State, Tribal, and territorial health depart-  
4 ments, laboratories, hospitals and other health care  
5 providers, electronic health records vendors, and  
6 other entities, as applicable and appropriate, in  
7 order to prepare for, identify, monitor, and respond  
8 to declared or potential public health emergencies.

9 (3) REPORT.—Not later than 90 days after the  
10 date of enactment of this Act, the Secretary shall re-  
11 port to the Committee on Health, Education, Labor,  
12 and Pensions of the Senate and the Committee on  
13 Energy and Commerce of the House of Representa-  
14 tives on the status of the agreements under this sub-  
15 section.

16 (d) IMPROVING INFORMATION SHARING AND AVAIL-  
17 ABILITY OF PUBLIC HEALTH DATA.—Part A of title III  
18 of the Public Health Service Act (42 U.S.C. 241 et seq.)  
19 is amended by adding at the end the following:

20 **“SEC. 310B. IMPROVING INFORMATION SHARING AND**  
21 **AVAILABILITY OF PUBLIC HEALTH DATA.**

22 “(a) IN GENERAL.—The Secretary may, in consulta-  
23 tion with State, local, and Tribal public health officials,  
24 carry out activities to improve the availability of appro-  
25 priate and applicable public health data related to commu-

1 nicable diseases, and information sharing between, the Di-  
2 rector of the Centers for Disease Control and Prevention,  
3 the Assistant Secretary for Preparedness and Response,  
4 and such State, local, and Tribal public health officials,  
5 which may include such data from—

6           “(1) health care providers and facilities;

7           “(2) public health and clinical laboratories; and

8           “(3) State, local, and Tribal health depart-  
9       ments.

10       “(b) CONTENT, FORM, AND MANNER.—The Sec-  
11 retary shall, consistent with the requirements of this sec-  
12 tion, work with such officials and relevant stakeholders to  
13 provide information on the content, form, and manner in  
14 which such data may most effectively support the ability  
15 of State, local, and Tribal health departments to respond  
16 to such communicable diseases, including related to the  
17 collection and reporting of demographic and other relevant  
18 data elements.

19       “(c) DECREASED BURDEN.—In facilitating the co-  
20 ordination of efforts under subsection (a), the Secretary  
21 shall make reasonable efforts to limit reported public  
22 health data to the minimum necessary information needed  
23 to accomplish the intended public health surveillance pur-  
24 pose.



1       “(d) EXEMPTION OF CERTAIN PUBLIC HEALTH  
2 DATA FROM DISCLOSURE.—The Secretary, acting  
3 through the Director of the Centers for Disease Control  
4 and Prevention, may exempt from disclosure under section  
5 552(b)(3) of title 5, United States Code, public health  
6 data that are gathered under this section if—

7           “(1) an individual is identified through such  
8 data; or

9           “(2) there is at least a very small risk, as deter-  
10 mined by current scientific practices or statistical  
11 methods, that some combination of the information,  
12 the request, and other available data sources or the  
13 application of technology could be used to deduce  
14 the identity of an individual.”.

15       (e) IMPROVING PUBLIC HEALTH DATA COLLEC-  
16 TION.—

17           (1) IN GENERAL.—The Secretary of Health and  
18 Human Services (referred to in this subsection as  
19 the “Secretary”) shall award grants, contracts, or  
20 cooperative agreements to eligible entities for pur-  
21 poses of identifying, developing, or disseminating  
22 best practices in the collection of electronic health  
23 information and the use of designated data stand-  
24 ards and implementation specifications to improve  
25 the quality and completeness of data, including de-

1       mographic data, collected, accessed, or used for pub-  
2       lic health purposes and to address health disparities  
3       and related health outcomes.

4           (2) ELIGIBLE ENTITIES.—To be eligible to re-  
5       ceive an award under this subsection an entity  
6       shall—

7           (A) be a health care provider, academic  
8       medical center, community-based organization,  
9       State, local governmental entity, Indian Tribe  
10      or Tribal organization (as such terms are de-  
11      fined in section 4 of the Indian Self Determina-  
12      tion and Education Assistance Act (25 U.S.C.  
13      5304)), urban Indian organization (as defined  
14      in section 4 of the Indian Health Care Improve-  
15      ment Act (25 U.S.C. 1603)), or other appro-  
16      priate public or private nonprofit entity, or a  
17      consortia of any such entities; and

18          (B) submit an application to the Secretary  
19      at such time, in such manner, and containing  
20      such information as the Secretary may require.

21          (3) ACTIVITIES.—Entities receiving awards  
22      under this subsection shall use such award to de-  
23      velop and test best practices for training health care  
24      providers to use standards and implementation spec-  
25      ifications that assist in the capture, access, ex-

1 change, and use of electronic health information, in-  
2 cluding demographic information, disability status,  
3 veteran status, housing status, functional status,  
4 and other data elements. Such activities shall in-  
5 clude, at a minimum—

6 (A) improving, understanding, and using  
7 data standards and implementation specifica-  
8 tions;

9 (B) developing or identifying methods to  
10 improve communication with patients in a  
11 culturally- and linguistically-appropriate man-  
12 ner, including to better capture information re-  
13 lated to demographics of such individuals;

14 (C) developing methods for accurately cat-  
15 egorizing and recording patient responses using  
16 available data standards;

17 (D) educating providers regarding the util-  
18 ity of such information for public health pur-  
19 poses and the importance of accurate collection  
20 and recording of such data; and

21 (E) other activities, as the Secretary deter-  
22 mines appropriate.

23 (4) REPORTING.—

24 (A) REPORTING BY AWARD RECIPIENTS.—

25 Each recipient of an award under this sub-

1 section shall submit to the Secretary a report  
2 on the results of best practices identified, devel-  
3 oped, or disseminated through such award.

4 (B) REPORT TO CONGRESS.—Not later  
5 than 1 year after the completion of the program  
6 under this subsection, the Secretary shall sub-  
7 mit a report to Congress on the success of best  
8 practices developed under such program, oppor-  
9 tunities for further dissemination of such best  
10 practices, and recommendations for improving  
11 the capture, access, exchange, and use of infor-  
12 mation to improve public health and reduce  
13 health disparities.

14 (5) NON-DUPLICATION OF EFFORTS.—The Sec-  
15 retary shall ensure that the activities and programs  
16 carried out under this subsection are free of unnec-  
17 essary duplication of effort.

18 (6) AUTHORIZATION OF APPROPRIATIONS.—  
19 There are authorized to be appropriated  
20 \$10,000,000 for each of fiscal years 2023 through  
21 2025 to carry out this subsection.

1 **SEC. 214. EPIDEMIC FORECASTING AND OUTBREAK ANA-**  
2 **LYTICS.**

3 Title XXVIII of the Public Health Service Act (42  
4 U.S.C. 300hh et seq.), as amended by section 212, is fur-  
5 ther amended by adding at the end the following:

6 **“SEC. 2825. EPIDEMIC FORECASTING AND OUTBREAK ANA-**  
7 **LYTICS.**

8 “(a) IN GENERAL.—The Secretary, acting through  
9 the Director of the Centers for Disease Control and Pre-  
10 vention, shall continue activities related to the develop-  
11 ment of infectious disease outbreak analysis capabilities  
12 to enhance the prediction, modeling, and forecasting of po-  
13 tential public health emergencies and other infectious dis-  
14 ease outbreaks, which may include activities to support  
15 preparedness for, and response to, such emergencies and  
16 outbreaks. In carrying out this subsection, the Secretary  
17 shall identify strategies to include and leverage, as appro-  
18 priate, the capabilities to public and private entities, which  
19 may include conducting such activities through collabo-  
20 rative partnerships with public and private entities, includ-  
21 ing academic institutions, and other Federal agencies, con-  
22 sistent with section 319D, as applicable.

23 “(b) CONSIDERATIONS.—In carrying out subsection  
24 (a), the Secretary, acting through the Director of the Cen-  
25 ters for Disease Control and Prevention, may consider  
26 public health data and, as appropriate, other data sources

1 related to the transmission of such infectious diseases that  
2 affect preparedness for, or response to, public health  
3 emergencies and infectious disease outbreaks.

4 “(c) ANNUAL REPORTS.—Not later than 1 year after  
5 the date of enactment of this section, and annually there-  
6 after for each of the subsequent 4 years, the Secretary  
7 shall prepare and submit a report, to the Committee on  
8 Health, Education, Labor, and Pensions of the Senate and  
9 the Committee on Energy and Commerce of the House  
10 of Representatives, regarding an update on progress on  
11 activities conducted under this section to develop infec-  
12 tious disease outbreak analysis capabilities and any addi-  
13 tional information relevant to such efforts.”.

14 **SEC. 215. REPORT ON CDC DATA PORTAL.**

15 (a) IN GENERAL.—Not later than 2 years after the  
16 date of enactment of this Act, the Secretary of Health and  
17 Human Services, acting through the Director of the Cen-  
18 ters for Disease Control and Prevention, shall submit a  
19 report to the Committee on Health, Education, Labor, and  
20 Pensions of the Senate and the Committee on Energy and  
21 Commerce of the House of Representatives regarding pub-  
22 lic health data modernization initiatives, surveillance in-  
23 vestments, and public health data reporting modernization  
24 initiatives under this Act (including the amendments made  
25 by this Act) and the Public Health Service Act (42 U.S.C.

1 201 et seq.), and provide recommendations on the feasi-  
2 bility of the use of a web-based information technology  
3 platform (referred to in this section as the “platform”)  
4 for the streamlining of existing voluntary submissions of  
5 public health data for all State, local, Tribal, and terri-  
6 torial entities that report such data to the Centers for Dis-  
7 ease Control and Prevention, and whether such platform  
8 would reduce the reporting burden for such entities.

9 (b) REQUIREMENTS.—The report under subsection  
10 (a) shall address the extent to which the submission of  
11 such data to the platform may—

12 (1) support coordination within the Department  
13 of Health and Human Services;

14 (2) provide appropriate information among and  
15 between State, Tribal, local, and territorial public  
16 health officials;

17 (3) leverage private sector technologies; and

18 (4) provide for the streamlining of data report-  
19 ing to the greatest extent possible.

20 **SEC. 216. PUBLIC HEALTH DATA TRANSPARENCY.**

21 (a) REPORT.—Not later than 1 year after the date  
22 of enactment of this Act, the Secretary of Health and  
23 Human Services shall issue a report assessing practices,  
24 objectives, and associated progress and challenges in  
25 achieving such objectives, of the Centers of Disease Con-

1 trol and Prevention with respect to the collection and dis-  
2 semination of public health data related to a public health  
3 emergency declared under section 319 of the Public  
4 Health Service Act (42 U.S.C. 247d) or a potential public  
5 health emergency.

6 (b) PLAN.—Not later than 180 days following the  
7 issuance of the report pursuant to paragraph (1), the Di-  
8 rector of the Centers for Disease Control and Prevention  
9 shall submit to the Committee on Health, Education,  
10 Labor, and Pensions of the Senate and the Committee on  
11 Energy and Commerce of the House of Representatives  
12 a plan that shall include—

13 (1) steps to improve the timely reporting and  
14 dissemination of public health data related to a pub-  
15 lic health emergency declared under section 319 of  
16 the Public Health Service Act (42 U.S.C. 247d) or  
17 a potential public health emergency that is collected  
18 by the Centers for Disease Control and Prevention,  
19 including any associated barriers;

20 (2) recommendations to Congress regarding  
21 gaps in such practices and objectives described in  
22 subsection (a); and

23 (3) considerations regarding the requirements  
24 and limitations of data use agreements for such pur-  
25 poses, as applicable.



1 **Subtitle C—Revitalizing the Public**  
2 **Health Workforce**

3 **SEC. 221. IMPROVING RECRUITMENT AND RETENTION OF**  
4 **THE FRONTLINE PUBLIC HEALTH WORK-**  
5 **FORCE.**

6 (a) IN GENERAL.—Section 776 of the Public Health  
7 Service Act (42 U.S.C. 295f–1) is amended—

8 (1) in subsection (a)—

9 (A) by striking “supply of” and inserting  
10 “supply of, and encourage recruitment and re-  
11 tention of,”; and

12 (B) by striking “Federal,”;

13 (2) in subsection (b)—

14 (A) by amending paragraph (1)(A) to read  
15 as follows:

16 “(1)(A)(i) be accepted for enrollment, or be en-  
17 rolled, as a student in an accredited institution of  
18 higher education or school of public health in the  
19 final semester (or equivalent) of a program leading  
20 to a certificate or degree, including a master’s or  
21 doctoral degree, in public health, epidemiology, lab-  
22 oratory sciences, data systems, data science, data  
23 analytics, informatics, statistics, or another subject  
24 matter related to public health; and

1           “(ii) be employed by, or have accepted employ-  
2           ment with, a State, local, or Tribal public health  
3           agency, or a related training fellowship at such  
4           State, local, or Tribal public health agency, as recog-  
5           nized by the Secretary, to commence upon gradua-  
6           tion; or”; and

7                   (B) in paragraph (1)(B)—

8                           (i) in clause (i)—

9                                   (I) by striking “accredited edu-  
10                                   cational institution in a State or terri-  
11                                   tory” and inserting “accredited insti-  
12                                   tution of higher education or school of  
13                                   public health”; and

14                                   (II) by striking “a public health  
15                                   or health professions degree or certifi-  
16                                   cate” and inserting “a certificate or  
17                                   degree, including a master’s or doc-  
18                                   toral degree, in public health, epidemi-  
19                                   ology, laboratory sciences, data sys-  
20                                   tems, data science, data analytics,  
21                                   informatics, statistics, or another sub-  
22                                   ject matter related to public health”;  
23                                   and

24                           (ii) in clause (ii)—

25                                   (I) by striking “Federal,”; and

1 (II) by striking “fellowship,” and  
2 inserting “fellowship at such State,  
3 local, or Tribal public health agency,”;

4 (3) in subsection (c)(2)—

5 (A) by striking “Federal,”; and

6 (B) by striking “equal to the greater of—  
7 ” and all that follows through the end of sub-  
8 paragraph (B) and inserting “of at least 3 con-  
9 secutive years,”;

10 (4) in subsection (d)—

11 (A) by amending paragraph (1) to read as  
12 follows:

13 “(1) IN GENERAL.—A loan repayment provided  
14 for an individual under a written contract under the  
15 Program shall consist of payment, in accordance  
16 with paragraph (2), for the individual toward the  
17 outstanding principal and interest on education  
18 loans incurred by the individual in the pursuit of the  
19 relevant degree or certificate described in subsection  
20 (b)(1) in accordance with the terms of the con-  
21 tract.”; and

22 (B) in paragraph (2)—

23 (i) by striking “For each year” and  
24 inserting the following:

25 “(A) IN GENERAL.—For each year”;

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

3 (iii) by striking “\$105,000” and in-  
4 sserting “\$150,000”; and

5 (iv) by adding at the end the fol-  
6 lowing:

7 “(B) CONSIDERATIONS.—The Secretary  
8 may take action in making awards under this  
9 section to ensure that—

10 “(i) an appropriate proportion of con-  
11 tracts are awarded to individuals who are  
12 eligible to participate in the program pur-  
13 suant to subsection (b)(1)(A); and

14 “(ii) contracts awarded under this  
15 section are equitably distributed among—

16 “(I) the geographical regions of  
17 the United States;

18 “(II) local, State, and Tribal  
19 public health departments; and

20 “(III) such public health depart-  
21 ments under subelause (II) serving  
22 rural and urban areas.”;

23 (5) in subsection (e), by striking “receiving a  
24 degree or certificate from a health professions or

1 other related school” and inserting “with a contract  
2 to serve under subsection (c)”;

3 (6) in subsection (f), by adding at the end the  
4 following: “In the event that a participant fails to ei-  
5 ther begin or complete the obligated service require-  
6 ment of the loan repayment contract under this sec-  
7 tion, the Secretary may waive or suspend either the  
8 unfulfilled service or the assessed damages as pro-  
9 vided for under section 338E(d), as appropriate.”;

10 (7) by redesignating subsection (g) as sub-  
11 section (h);

12 (8) by inserting after subsection (f) the fol-  
13 lowing:

14 “(g) ELIGIBLE LOANS.—The loans eligible for repay-  
15 ment under this section are each of the following:

16 “(1) Any loan for education or training for em-  
17 ployment by a health department.

18 “(2) Any loan under part E of title VIII (relat-  
19 ing to nursing student loans).

20 “(3) Any Federal Direct Stafford Loan, Fed-  
21 eral Direct PLUS Loan, Federal Direct Unsub-  
22 sidized Stafford Loan, or Federal Direct Consolida-  
23 tion Loan (as such terms are used in section 455 of  
24 the Higher Education Act of 1965).

1           “(4) Any Federal Perkins Loan under part E  
2 of title I of the Higher Education Act of 1965.

3           “(5) Any other Federal loan, as the Secretary  
4 determines appropriate.”;

5           (9) in subsection (h), as so redesignated, by  
6 striking “\$195,000,000 for fiscal year 2010, and  
7 such sums as may be necessary for each of fiscal  
8 years 2011 through 2015” and inserting “such sums  
9 as may be necessary for each of fiscal years 2022  
10 through 2025”; and

11           (10) by striking “tribal” each place such term  
12 appears and inserting “Tribal”.

13           (b) GAO STUDY ON PUBLIC HEALTH WORKFORCE  
14 .—Not later than 2 years after the date of enactment of  
15 this Act, the Comptroller General of the United States  
16 shall—

17           (1) conduct an evaluation of what is known  
18 about the public health workforce in the United  
19 States, which shall address—

20           (A) existing gaps in the Federal, State,  
21 local, Tribal, and territorial public health work-  
22 force, including positions that may be required  
23 to prepare for, and respond to, a public health  
24 emergency such as COVID–19;

1 (B) challenges associated with the hiring,  
 2 recruitment, and retention of the Federal,  
 3 State, local, Tribal, and territorial public health  
 4 workforce; and

5 (C) Federal efforts to improve hiring, re-  
 6 cruitment, and retention of the public health  
 7 workforce; and

8 (2) submit to the Committee on Health, Edu-  
 9 cation, Labor, and Pensions of the Senate and the  
 10 Committee on Energy and Commerce of the House  
 11 of Representatives a report on such review.

12 **SEC. 222. AWARDS TO SUPPORT COMMUNITY HEALTH**  
 13 **WORKERS AND COMMUNITY HEALTH.**

14 (a) IN GENERAL.—Section 399V of the Public  
 15 Health Service Act (42 U.S.C. 280g–11) is amended—

16 (1) by amending the section heading to read as  
 17 follows: “**AWARDS TO SUPPORT COMMUNITY**  
 18 **HEALTH WORKERS AND COMMUNITY HEALTH**”;

19 (2) by amending subsection (a) to read as fol-  
 20 lows:

21 “(a) IN GENERAL.—The Secretary, acting through  
 22 the Director of the Centers for Disease Control and Pre-  
 23 vention and in coordination with the Administrator of the  
 24 Health Resources and Services Administration, shall  
 25 award grants, contracts, or cooperative agreements to eli-

1 gible entities to promote positive health behaviors and out-  
2 comes for populations in medically underserved commu-  
3 nities by leveraging community health workers, including  
4 by addressing ongoing and longer-term community health  
5 needs, and by building the capacity of the community  
6 health worker workforce. Such grants, contracts, and co-  
7 operative agreements shall be awarded in alignment and  
8 coordination with existing funding arrangements sup-  
9 porting community health workers.”;

10 (3) in subsection (b)—

11 (A) in the matter preceding paragraph

12 (1)—

13 (i) by striking “Grants awarded” and  
14 inserting “Subject to any requirements for  
15 the scope of licensure, registration, or cer-  
16 tification of a community health worker  
17 under applicable State law, grants, con-  
18 tracts, and cooperative agreements award-  
19 ed”; and

20 (ii) by striking “support community  
21 health workers”;

22 (B) by redesignating paragraphs (3)  
23 through (5) as paragraphs (4) through (6), re-  
24 spectively;



1 (C) by striking paragraphs (1) and (2) and  
2 inserting the following:

3 “(1) recruit, hire, train, and retain community  
4 health workers that reflect the needs of the commu-  
5 nity;

6 “(2) support community health workers in pro-  
7 viding education and outreach, in a community set-  
8 ting, regarding—

9 “(A) health conditions prevalent in—

10 “(i) medically underserved commu-  
11 nities (as defined in section 799B), par-  
12 ticularly racial and ethnic minority popu-  
13 lations; and

14 “(ii) other such at-risk populations or  
15 geographic areas that may require addi-  
16 tional support during public health emer-  
17 gencies, which may include counties identi-  
18 fied by the Secretary using applicable  
19 measures developed by the Centers for Dis-  
20 ease Control and Prevention or other Fed-  
21 eral agencies; and

22 “(B) addressing social determinants of  
23 health and eliminating health disparities, in-  
24 cluding by—

1           “(i) promoting awareness of services  
2           and resources to increase access to health  
3           care, mental health and substance use dis-  
4           order services, child services, technology,  
5           housing services, educational services, nu-  
6           trition services, employment services, and  
7           other services; and

8           “(ii) assisting in conducting individual  
9           and community needs assessments;

10           “(3) educate community members, including re-  
11           garding effective strategies to promote healthy be-  
12           haviors;”;

13           (D) in paragraph (4), as so redesignated,  
14           by striking “to educate” and inserting “edu-  
15           cate”;

16           (E) in paragraph (5), as so redesignated—

17           (i) by striking “to identify” and in-  
18           serting “identify”;

19           (ii) by striking “healthcare agencies”  
20           and inserting “health care agencies”; and

21           (iii) by striking “healthcare services  
22           and to eliminate duplicative care; or” and  
23           inserting “health care services and to  
24           streamline care, including serving as a liai-

1 son between communities and health care  
2 agencies; and”;

3 (F) in paragraph (6), as so redesignated—

4 (i) by striking “to educate, guide, and  
5 provide” and inserting “support commu-  
6 nity health workers in educating, guiding,  
7 or providing”;

8 (ii) by striking “maternal health and  
9 prenatal care” and inserting “chronic dis-  
10 eases, maternal health, prenatal, and  
11 postpartum care in order to improve ma-  
12 ternal and infant health outcomes”;

13 (4) in subsection (c), by striking “Each eligible  
14 entity” and all that follows through “accompanied  
15 by” and inserting “To be eligible to receive an  
16 award under subsection (a), an entity shall prepare  
17 and submit to the Secretary an application at such  
18 time, in such manner, and containing”;

19 (5) in subsection (d)—

20 (A) in the matter preceding paragraph (1),  
21 by striking “awarding grants” and inserting  
22 “making awards”;

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

25 “(1) propose to serve—

1           “(A) areas with populations that have a  
2 high rate of chronic disease, infant mortality, or  
3 maternal morbidity and mortality;

4           “(B) low-income populations, including  
5 medically underserved populations (as defined  
6 in section 330(b)(3));

7           “(C) populations residing in health profes-  
8 sional shortage areas (as defined in section  
9 332(a));

10           “(D) populations residing in maternity  
11 care health professional target areas identified  
12 under section 332(k); or

13           “(E) rural or traditionally underserved  
14 populations, including racial and ethnic minor-  
15 ity populations or low-income populations;”;

16           (C) in paragraph (2), by striking “; and”  
17 and inserting “, including rural populations and  
18 racial and ethnic minority populations;”;

19           (D) in paragraph (3), by striking “with  
20 community health workers.” and inserting “and  
21 established relationships with community health  
22 workers in the communities expected to be  
23 served by the program;” and

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

1           “(4) develop a plan for providing services to the  
2 extent practicable, in the language and cultural con-  
3 text most appropriate to individuals expected to be  
4 served by the program; and

5           “(5) propose to use evidence-informed or evi-  
6 dence-based practices, as applicable and appro-  
7 priate.”;

8           (6) in subsection (e)—

9           (A) by striking “community health worker  
10 programs” and inserting “eligible entities”; and

11           (B) by striking “and one-stop delivery sys-  
12 tems under section 121(e)” and inserting “,  
13 health professions schools, minority-serving in-  
14 stitutions (defined, for purposes of this sub-  
15 section, as institutions and programs described  
16 in section 326(e)(1) of the Higher Education  
17 Act of 1965 and institutions described in sec-  
18 tion 371(a) of such Act), area health education  
19 centers under section 751 of this Act, and one-  
20 stop delivery systems under section 121”;

21           (7) by striking subsections (f), (g), (h), (i), and  
22 (j) and inserting the following:

23           “(f) TECHNICAL ASSISTANCE.—The Secretary may  
24 provide to eligible entities that receive awards under sub-  
25 section (a) technical assistance with respect to planning,

1 development, and operation of community health worker  
2 programs authorized or supported under this section.

3       “(g) DISSEMINATION OF BEST PRACTICES.—Not  
4 later than 4 years after the date of enactment of the PRE-  
5 VENT Pandemics Act, the Secretary shall, based on ac-  
6 tivities carried out under this section and in consultation  
7 with relevant stakeholders, identify and disseminate evi-  
8 dence-based or evidence-informed practices regarding re-  
9 cruitment and retention of community health workers and  
10 paraprofessionals to address ongoing public health and  
11 community health needs, and to prepare for, and respond  
12 to, future public health emergencies.

13       “(h) REPORT TO CONGRESS.—Not later than 4 years  
14 after the date of enactment of the PREVENT Pandemics  
15 Act, the Secretary shall submit to the Committee on  
16 Health, Education, Labor, and Pensions of the Senate and  
17 the Committee on Energy and Commerce of the House  
18 of Representatives a report concerning the effectiveness of  
19 the program under this section in addressing ongoing pub-  
20 lic health and community health needs. Such report shall  
21 include recommendations regarding any improvements to  
22 such program, including recommendations for how to im-  
23 prove recruitment, training, and retention of the commu-  
24 nity health workforce.

1       “(i) AUTHORIZATION OF APPROPRIATIONS.—For  
2 purposes of carrying out this section, there are authorized  
3 to be appropriated such sums as may be necessary for  
4 each of fiscal years 2023 through 2027.”;

5           (8) by redesignating subsection (k) as sub-  
6 section (j); and

7           (9) in subsection (j), as so redesignated—

8               (A) by striking paragraphs (1), (2), and  
9               (4);

10              (B) by redesignating paragraph (3) as  
11 paragraph (1);

12              (C) in paragraph (1), as so redesignated—

13                   (i) by striking “entity (including a  
14 State or public subdivision of a State” and  
15 inserting “entity, including a State or po-  
16 litical subdivision of a State, an Indian  
17 Tribe or Tribal organization, an urban In-  
18 dian organization, a community-based or-  
19 ganization”; and

20                   (ii) by striking “as defined in section  
21 1861(aa) of the Social Security Act))” and  
22 inserting “(as defined in section  
23 1861(aa)(4) of the Social Security Act)”;  
24 and

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

1           “(2) INDIAN TRIBE; TRIBAL ORGANIZATION.—  
2           The terms ‘Indian Tribe’ and ‘Tribal organization’  
3           have the meanings given the terms ‘Indian tribe’ and  
4           ‘tribal organization’, respectively, in section 4 of the  
5           Indian Self-Determination and Education Assistance  
6           Act.

7           “(3) URBAN INDIAN ORGANIZATION.—The term  
8           ‘urban Indian organization’ has the meaning given  
9           such term in section 4 of the Indian Health Care  
10          Improvement Act.”.

11          (b) GAO STUDY AND REPORT.—Not later than 1  
12         year after the date of submission of the report under sub-  
13         section (h) of section 399V of the Public Health Service  
14         Act (42 U.S.C. 280g–11), as amended by subsection (a),  
15         the Comptroller General of the United States shall submit  
16         to the Committee on Health, Education, Labor, and Pen-  
17         sions of the Senate and the Committee on Energy and  
18         Commerce of the House of Representatives a report on  
19         the program authorized under such section 399V, includ-  
20         ing a review of the efforts of the Secretary of Health and  
21         Human Services to coordinate such program with applica-  
22         ble programs of the Health Resources and Services Ad-  
23         ministration to ensure there is no unnecessary duplication  
24         of efforts among such programs, and identification of any  
25         areas of duplication.



1 **SEC. 223. IMPROVING PUBLIC HEALTH EMERGENCY RE-**  
2 **SPONSE CAPACITY.**

3 (a) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC  
4 HEALTH EMERGENCY RESPONSES.—Section 319 of the  
5 Public Health Service Act (42 U.S.C. 247d) is amended  
6 by adding at the end the following:

7 “(g) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC  
8 HEALTH EMERGENCY RESPONSES.—

9 “(1) IN GENERAL.—In order to support the ini-  
10 tial response to a public health emergency declared  
11 by the Secretary under this section, the Secretary  
12 may, subject to paragraph (2) and without regard to  
13 sections 3309 through 3318 of title 5, United States  
14 Code, appoint individuals directly to positions in the  
15 Department of Health and Human Services for  
16 which the Secretary has provided public notice in  
17 order to—

18 “(A) address a critical hiring need directly  
19 related to responding to a public health emer-  
20 gency declared by the Secretary under this sec-  
21 tion; or

22 “(B) address a severe shortage of can-  
23 didates that impacts the operational capacity of  
24 the Department of Health and Human Services  
25 to respond in the event of a public health emer-

1           agency declared by the Secretary under this sec-  
2           tion.

3           “(2) NUMBER OF APPOINTMENTS.—Each fiscal  
4           year in which the Secretary makes a determination  
5           of a public health emergency under subsection (a)  
6           (not including a renewal), the Secretary may directly  
7           appoint not more than—

8                   “(A) 400 individuals under paragraph  
9                   (1)(A); and

10                   “(B) 100 individuals under paragraph  
11                   (1)(B).

12           “(3) COMPENSATION.—The annual rate of  
13           basic pay of an individual appointed under this sub-  
14           section shall be determined in accordance with chap-  
15           ter 51 and subchapter III of chapter 53 of title 5,  
16           United States Code.

17           “(4) REPORTING.—The Secretary shall estab-  
18           lish and maintain records regarding the use of the  
19           authority under this subsection, including—

20                   “(A) the number of positions filled through  
21                   such authority;

22                   “(B) the types of appointments of such po-  
23                   sitions;

24                   “(C) the titles, occupational series, and  
25                   grades of such positions;

1           “(D) the number of positions publicly no-  
2           ticed to be filled under such authority;

3           “(E) the number of qualified applicants  
4           who apply for such positions;

5           “(F) the qualification criteria for such po-  
6           sitions; and

7           “(G) the demographic information of indi-  
8           viduals appointed to such positions.

9           “(5) NOTIFICATION TO CONGRESS.—In the  
10          event the Secretary, within a single fiscal year, di-  
11          rectly appoints more than 50 percent of the individ-  
12          uals allowable under either subparagraph (A) or (B)  
13          of paragraph (2), the Secretary shall, not later than  
14          15 days after the date of such action, notify the  
15          Committee on Health, Education, Labor, and Pen-  
16          sions of the Senate and the Committee on Energy  
17          and Commerce of the House of Representatives.  
18          Such notification shall, in a manner that protects  
19          personal privacy, to the extent required by applicable  
20          Federal and State privacy law, at a minimum, in-  
21          clude—

22                 “(A) information on each such appoint-  
23                 ment within such fiscal year;

1           “(B) a description of how each such posi-  
2           tion relates to the requirements of subpara-  
3           graph (A) or (B) of paragraph (1); and

4           “(C) the additional number of personnel, if  
5           any, the Secretary anticipates to be necessary  
6           to adequately support a response to a public  
7           health emergency declared under this section  
8           using the authorities described in paragraph (1)  
9           within such fiscal year.

10          “(6) REPORTS TO CONGRESS.—Not later than  
11          September 30, 2023, and annually thereafter for  
12          each fiscal year in which the authority under this  
13          subsection is used, the Secretary shall submit to the  
14          Committee on Health, Education, Labor, and Pen-  
15          sions of the Senate and the Committee on Energy  
16          and Commerce of the House of Representatives a re-  
17          port describing the total number of appointments  
18          filled under this subsection within the fiscal year and  
19          a description of how the positions relate to the re-  
20          quirements of subparagraph (A) or (B) of paragraph  
21          (1).

22          “(7) SUNSET.—The authority under this sub-  
23          section shall expire on September 30, 2028.”.

24          (b) GAO REPORT.—Not later than 1 year after the  
25          issuance of the initial report under subsection (g)(6) of

1 section 319 of the Public Health Service Act (42 U.S.C.  
2 247d), as added by subsection (a), and again 180 days  
3 after the date on which the authority provided under sec-  
4 tion 319(g) of such Act expires pursuant to paragraph (7)  
5 of such section, the Comptroller General of the United  
6 States shall submit to the Committee on Health, Edu-  
7 cation, Labor, and Pensions of the Senate and the Com-  
8 mittee on Energy and Commerce of the House of Rep-  
9 resentatives a report on the use of the authority provided  
10 under such section. Such report shall, in a manner that  
11 protects personal privacy, at a minimum, include informa-  
12 tion on—

13 (1) the number of positions publicly noticed and  
14 filled under the authority of each of subparagraphs  
15 (A) and (B) of such section 319(g)(1);

16 (2) the occupational series, grades, and types of  
17 appointments of such positions;

18 (3) how such positions related to addressing a  
19 need or shortage described in subparagraph (A) or  
20 (B) of such section;

21 (4) how the Secretary of Health and Human  
22 Services made appointment decisions under each of  
23 subparagraphs (A) and (B) of such section;

24 (5) sources used to identify candidates for fill-  
25 ing such positions;

1           (6) the number of individuals appointed under  
2 each such subparagraph;

3           (7) aggregated demographic information related  
4 to individuals appointed under each such subpara-  
5 graph; and

6           (8) any challenges, limitations, or gaps related  
7 to the use of the authority under each such subpara-  
8 graph and any related recommendations to address  
9 such challenges, limitations, or gaps.

10 **SEC. 224. EXTENSION OF AUTHORITIES TO SUPPORT**  
11 **HEALTH PROFESSIONAL VOLUNTEERS AT**  
12 **COMMUNITY HEALTH CENTERS.**

13           Section 224(q) of the Public Health Service Act (42  
14 U.S.C. 233(q)) is amended by striking paragraph (6).

15 **SEC. 225. INCREASING EDUCATIONAL OPPORTUNITIES FOR**  
16 **ALLIED HEALTH PROFESSIONS.**

17           Section 755(b) of the Public Health Service Act (42  
18 U.S.C. 294e(b)) is amended by adding at the end the fol-  
19 lowing:

20           “(4) Increasing educational opportunities in  
21 physical therapy, occupational therapy, respiratory  
22 therapy, audiology, and speech-language pathology  
23 professions, which may include offering scholarships  
24 or stipends and carrying out other activities to im-  
25 prove retention, for individuals from disadvantaged

1 backgrounds or individuals who are underrep-  
2 resented in such professions.”.

3 **SEC. 226. PUBLIC HEALTH SERVICE CORPS ANNUAL AND**  
4 **SICK LEAVE.**

5 (a) IN GENERAL.—Section 219 of the Public Health  
6 Service Act (42 U.S.C. 210–1) is amended—

7 (1) in subsection (a)—

8 (A) by striking “Reserve Corps” and in-  
9 serting “Ready Reserve Corps”; and

10 (B) by striking “: *Provided*, That such reg-  
11 ulations shall not authorize annual leave to be  
12 accumulated in excess of sixty days”;

13 (2) by inserting after subsection (a) the fol-  
14 lowing:

15 “(b) The regulations described in subsection (a) may  
16 authorize accumulated annual leave of not more than 120  
17 days for any commissioned officer of the Regular Corps  
18 or officer of the Ready Reserve Corps on active duty.”;  
19 and

20 (3) by redesignating subsection (d) as sub-  
21 section (c).

22 (b) APPLICATION.—The amendments made by sub-  
23 section (a) shall apply with respect to accumulated annual  
24 leave (as defined in section 219 of the Public Health Serv-  
25 ice Act (42 U.S.C. 210–1)) that a commissioned officer

1 of the Regular Corps or officer of the Ready Reserve  
2 Corps on active duty would, but for the regulations de-  
3 scribed in such section, lose at the end of fiscal year 2022  
4 or a subsequent fiscal year.

5           **Subtitle D—Improving Public**  
6                           **Health Responses**

7   **SEC. 231. CENTERS FOR PUBLIC HEALTH PREPAREDNESS**  
8                           **AND RESPONSE.**

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

11                   (1) by striking subsection (d) and inserting the  
12 following:

13           “(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS  
14 AND RESPONSE.—

15                   “(1) IN GENERAL.—The Secretary, acting  
16 through the Director of the Centers for Disease  
17 Control and Prevention, may award grants, con-  
18 tracts, or cooperative agreements to institutions of  
19 higher education, including accredited schools of  
20 public health, or other nonprofit private entities to  
21 establish or maintain a network of Centers for Pub-  
22 lic Health Preparedness and Response (referred to  
23 in this subsection as ‘Centers’).

24                   “(2) ELIGIBILITY.—To be eligible to receive an  
25 award under this subsection, an entity shall submit



1 to the Secretary an application containing such in-  
2 formation as the Secretary may require, including a  
3 description of how the entity will—

4 “(A) coordinate relevant activities with ap-  
5 plicable State, local, and Tribal health depart-  
6 ments and officials, health care facilities, and  
7 health care coalitions to improve public health  
8 preparedness and response, as informed by the  
9 public health preparedness and response needs  
10 of the community, or communities, involved;

11 “(B) prioritize efforts to implement evi-  
12 dence-informed or evidence-based practices to  
13 improve public health preparedness and re-  
14 sponse, including by helping to reduce the  
15 transmission of emerging infectious diseases;  
16 and

17 “(C) use funds awarded under this sub-  
18 section, including by carrying out any activities  
19 described in paragraph (3).

20 “(3) USE OF FUNDS.—The Centers established  
21 or maintained under this subsection shall use funds  
22 awarded under this subsection to carry out activities  
23 to advance public health preparedness and response  
24 capabilities, which may include—

1           “(A) identifying, translating, and dissemi-  
2           nating promising research findings or strategies  
3           into evidence-informed or evidence-based prac-  
4           tices to inform preparedness for, and responses  
5           to, chemical, biological, radiological, or nuclear  
6           threats, including emerging infectious diseases,  
7           and other public health emergencies, which may  
8           include conducting research related to public  
9           health preparedness and response systems;

10           “(B) improving awareness of such evi-  
11           dence-informed or evidence-based practices and  
12           other relevant scientific or public health infor-  
13           mation among health care professionals, public  
14           health professionals, other stakeholders, and the  
15           public, including through the development, eval-  
16           uation, and dissemination of trainings and  
17           training materials, consistent with section  
18           2802(b)(2), as applicable and appropriate, and  
19           with consideration given to existing training  
20           materials, to support preparedness for, and re-  
21           sponses to, such threats;

22           “(C) utilizing and expanding relevant tech-  
23           nological and analytical capabilities to inform  
24           public health and medical preparedness and re-  
25           sponse efforts;

1           “(D) expanding activities, including  
2 through public-private partnerships, related to  
3 public health preparedness and response, in-  
4 cluding participation in drills and exercises and  
5 training public health experts, as appropriate;  
6 and

7           “(E) providing technical assistance and ex-  
8 pertise that relies on evidence-based practices,  
9 as applicable, related to responses to public  
10 health emergencies, as appropriate, to State,  
11 local, and Tribal health departments and other  
12 entities pursuant to paragraph (2)(A).

13           “(4) DISTRIBUTION OF AWARDS.—In awarding  
14 grants, contracts, or cooperative agreements under  
15 this subsection, the Secretary shall support not  
16 fewer than 10 Centers, subject to the availability of  
17 appropriations, and ensure that such awards are eq-  
18 uitably distributed among the geographical regions  
19 of the United States.”; and

20           (2) in subsection (f)(1)(C), by striking “, of  
21 which \$5,000,000 shall be used to carry out para-  
22 graphs (3) through (5) of such subsection”.

23           (b) REPEAL.—Section 319G of the Public Health  
24 Service Act (42 U.S.C. 247d–7) is repealed.

1 **SEC. 232. VACCINE DISTRIBUTION PLANS.**

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

4 (1) in subsection (a)—

5 (A) by inserting “, or other federally pur-  
6 chased vaccine to address another pandemic”  
7 before the period at the end of the first sen-  
8 tence; and

9 (B) by inserting “or other pandemic” be-  
10 fore the period at the end of the second sen-  
11 tence; and

12 (2) in subsection (d), by inserting “or other  
13 pandemics” after “influenza pandemics”.

14 **SEC. 233. COORDINATION AND COLLABORATION REGARD-**  
15 **ING BLOOD SUPPLY.**

16 (a) IN GENERAL.—The Secretary of Health and  
17 Human Services, or the Secretary’s designee, shall—

18 (1) ensure coordination and collaboration be-  
19 tween relevant Federal departments and agencies re-  
20 lated to the safety and availability of the blood sup-  
21 ply, including—

22 (A) the Department of Health and Human  
23 Services, including the Office of the Assistant  
24 Secretary for Health, the Centers for Disease  
25 Control and Prevention, the Food and Drug  
26 Administration, the Office of the Assistant Sec-

1           retary for Preparedness and Response, the Na-  
2           tional Institutes of Health, the Centers for  
3           Medicare & Medicaid Services, and the Health  
4           Resources and Services Administration;

5                   (B) the Department of Defense; and

6                   (C) the Department of Veterans Affairs;

7           and

8           (2) consult and communicate with private  
9           stakeholders, including blood collection establish-  
10          ments, health care providers, accreditation organiza-  
11          tions, researchers, and patients, regarding issues re-  
12          lated to the safety and availability of the blood sup-  
13          ply.

14          (b) STREAMLINING BLOOD DONOR INPUT.—Chapter  
15          35 of title 44, United States Code, shall not apply to the  
16          collection of information to which a response is voluntary  
17          and that is initiated by the Secretary of Health and  
18          Human Services to solicit information from blood donors  
19          or potential blood donors to support the development of  
20          recommendations by the Secretary concerning blood dona-  
21          tion.

1 **TITLE III—ACCELERATING RE-**  
2 **SEARCH AND COUNTER-**  
3 **MEASURE DISCOVERY**

4 **Subtitle A—Fostering Research**  
5 **and Development and Improv-**  
6 **ing Coordination**

7 **SEC. 301. RESEARCH AND ACTIVITIES RELATED TO LONG-**  
8 **TERM HEALTH EFFECTS OF SARS-COV-2 IN-**  
9 **FECTION.**

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

13 (1) continue to conduct or support basic, clin-  
14 ical, epidemiological, behavioral, and translational  
15 research and public health surveillance related to the  
16 pathogenesis, prevention, diagnosis, and treatment  
17 of the long-term health effects of SARS-CoV-2 in-  
18 fection; and

19 (2) in consultation with health professional as-  
20 sociations, researchers, and other relevant experts,  
21 develop and inform recommendations, guidance, and  
22 provide educational materials for health care pro-  
23 viders and the general public on the long-term ef-  
24 fects of SARS-CoV-2 infection, consistent with the

1 findings of studies and research under paragraph  
2 (1).

3 (b) CONSIDERATIONS.—In conducting or supporting  
4 research under this section, the Secretary shall consider  
5 the diversity of research participants or cohorts to ensure  
6 inclusion of a broad range of participants, as applicable  
7 and appropriate.

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

19 **SEC. 302. RESEARCH CENTERS FOR PATHOGENS OF PAN-**  
20 **DEMIC CONCERN.**

21 Subpart 6 of part C of title IV of the Public Health  
22 Service Act is amended by inserting after section 447C  
23 (42 U.S.C. 285f–4) the following:

1 **“SEC. 447D. RESEARCH CENTERS FOR PATHOGENS OF PAN-**  
2 **DEMIC CONCERN.**

3 “(a) IN GENERAL.—The Director of the Institute, in  
4 collaboration, as appropriate, with the directors of applica-  
5 ble institutes, centers, and divisions of the National Insti-  
6 tutes of Health, the Assistant Secretary for Preparedness  
7 and Response, and the Director of the Biomedical Ad-  
8 vanced Research and Development Authority, shall estab-  
9 lish or continue a multidisciplinary research program to  
10 advance the discovery and preclinical development of med-  
11 ical products for priority virus families and other viral  
12 pathogens with a significant potential to cause a pan-  
13 demic, through support for research centers.

14 “(b) USES OF FUNDS.—The Director of the Institute  
15 shall award funding through grants, contracts, or coopera-  
16 tive agreements to public or private entities to provide  
17 support for research centers described in subsection (a)  
18 for the purpose of—

19 “(1) conducting basic research through pre-  
20 clinical development of new medical products or  
21 technologies, including platform technologies, to ad-  
22 dress pathogens of pandemic concern;

23 “(2) identifying potential targets for thera-  
24 peutic candidates, including antivirals, to treat such  
25 pathogens;



1           “(3) identifying existing medical products with  
2           the potential to address such pathogens, including  
3           candidates that could be used in outpatient settings;  
4           and

5           “(4) carrying out or supporting other research  
6           related to medical products to address such patho-  
7           gens, as determined appropriate by the Director.

8           “(c) COORDINATION.—The Director of the Institute  
9           shall, as appropriate, provide for the coordination of ac-  
10          tivities among the centers described in subsection (a), in-  
11          cluding through—

12           “(1) facilitating the exchange of information  
13           and regular communication among the centers, as  
14           appropriate; and

15           “(2) requiring the periodic preparation and sub-  
16           mission to the Director of reports on the activities  
17           of each center.

18           “(d) PRIORITY.—In awarding funding through  
19           grants, contracts, or cooperative agreements under sub-  
20           section (a), the Director of the Institute shall, as appro-  
21           priate, give priority to applicants with existing frameworks  
22           and partnerships, as applicable, to support the advance-  
23           ment of such research.

24           “(e) COLLABORATION.—The Director of the Institute  
25           shall—

1           “(1) collaborate with the heads of other appro-  
2           priate Federal departments, agencies, and offices  
3           with respect to the identification of additional pri-  
4           ority virus families and other viral pathogens with a  
5           significant potential to cause a pandemic; and

6           “(2) collaborate with the Director of the Bio-  
7           medical Advanced Research and Development Au-  
8           thority with respect to the research conducted by  
9           centers described in subsection (a), including, as ap-  
10          propriate, providing any updates on the research ad-  
11          vancements made by such centers, identifying any  
12          advanced research and development needs for such  
13          countermeasures, consistent with section  
14          319L(a)(6), and taking into consideration existing  
15          manufacturing capacity and future capacity needs  
16          for such medical products or technologies, including  
17          platform technologies, supported by the centers de-  
18          scribed in subsection (a).

19          “(f) SUPPLEMENT, NOT SUPPLANT.—Any support  
20          received by a center described in subsection (a) under this  
21          section shall be used to supplement, and not supplant,  
22          other public or private support for activities authorized to  
23          be supported.”.

1 **SEC. 303. IMPROVING MEDICAL COUNTERMEASURE RE-**  
2 **SEARCH COORDINATION.**

3 Section 402(b) in the Public Health Service Act (42  
4 U.S.C. 282(b)) is amended—

5 (1) in paragraph (24), by striking “and” at the  
6 end;

7 (2) in paragraph (25), by striking the period  
8 and inserting a semicolon; and

9 (3) by inserting after paragraph (25) the fol-  
10 lowing:

11 “(26) shall consult with the Assistant Secretary  
12 for Preparedness and Response, the Director of the  
13 Biomedical Advanced Research and Development  
14 Authority, the Director of the Centers for Disease  
15 Control and Prevention, and the heads of other Fed-  
16 eral agencies and offices, as appropriate, regarding  
17 research needs to advance medical countermeasures  
18 to diagnose, mitigate, prevent, or treat harm from  
19 any biological agent or toxin, including emerging in-  
20 fectious diseases, chemical, radiological, or nuclear  
21 agent that may cause a public health emergency or  
22 other research needs related to emerging public  
23 health threats;”.

1 **SEC. 304. ACCESSING SPECIMEN SAMPLES AND DIAG-**  
2 **NOSTIC TESTS.**

3 (a) IMPROVING RESEARCH AND DEVELOPMENT OF  
4 MEDICAL COUNTERMEASURES FOR NOVEL PATHO-  
5 GENS.—

6 (1) SAMPLE ACCESS.—Not later than 1 year  
7 after the date of enactment of this Act, the Sec-  
8 retary of Health and Human Services (referred to in  
9 this subsection as the “Secretary”) shall make pub-  
10 licly available policies and procedures related to pub-  
11 lic and private entities accessing specimens of, or  
12 specimens containing, pathogens or suitable surro-  
13 gates for, or alternatives to, such pathogens as the  
14 Secretary determines appropriate to support public  
15 health preparedness and response activities or bio-  
16 medical research for purposes of the development  
17 and validation, as applicable, of medical products to  
18 address emerging infectious diseases and for use to  
19 otherwise respond to emerging infectious diseases.  
20 Such policies and procedures shall take into account,  
21 as appropriate, any applicable existing Federal re-  
22 sources.

23 (2) GUIDANCE.—The Secretary shall issue  
24 guidance regarding the procedures for carrying out  
25 paragraph (1), including—

1 (A) the method for requesting such sam-  
2 ples;

3 (B) considerations for sample availability  
4 and use of suitable surrogates or alternatives to  
5 such pathogens, as appropriate, including appli-  
6 cable safeguard and security measures; and

7 (C) information required to be provided in  
8 order to receive such samples or suitable surro-  
9 gates or alternatives.

10 (b) EARLIER DEVELOPMENT OF DIAGNOSTIC  
11 TESTS.—Title III of the Public Health Service Act is  
12 amended by inserting after section 319A (42 U.S.C.  
13 247d–1) the following:

14 **“SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC**  
15 **TESTS.**

16 “The Secretary may contract with public and private  
17 entities, as appropriate, to increase capacity in the rapid  
18 development, validation, manufacture, and dissemination  
19 of diagnostic tests, as appropriate, to State, local, and  
20 Tribal health departments and other appropriate entities  
21 for immediate public health response activities to address  
22 an emerging infectious disease with respect to which a  
23 public health emergency is declared under section 319, or  
24 that has significant potential to cause such a public health  
25 emergency.”.

1     **Subtitle B—Improving Biosafety**  
2                     **and Biosecurity**

3     **SEC. 311. IMPROVING CONTROL AND OVERSIGHT OF SE-**  
4                     **LECT BIOLOGICAL AGENTS AND TOXINS.**

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

7                     (1) in subsection (b)(1), by amending subpara-  
8     graph (A) to read as follows:

9                             “(A) proper training, including with re-  
10                             spect to notification requirements under this  
11                             section, of—

12                                     “(i) individuals who are involved in  
13                                     the handling and use of such agents and  
14                                     toxins, including appropriate skills to han-  
15                                     dle such agents and toxins;

16                                     “(ii) individuals whose responsibilities  
17                                     routinely place them in close proximity to  
18                                     laboratory facilities in which such agents  
19                                     and toxins are being transferred, pos-  
20                                     sessed, or used; and

21                                     “(iii) individuals who perform admin-  
22                                     istrative or oversight functions of the facil-  
23                                     ity related to the transfer, possession, or  
24                                     use of such agents and toxins on behalf of  
25                                     registered persons;”;

1           (2) in subsection (e)(1), by striking “(including  
2           the risk of use in domestic or international ter-  
3           rorism)” and inserting “(including risks posed by  
4           the release, theft, or loss of such agent or toxin, or  
5           use in domestic or international terrorism)”;

6           (3) in subsection (k)—

7                 (A) by redesignating paragraphs (1) and  
8                 (2) as paragraphs (2) and (3), respectively;

9                 (B) by inserting before paragraph (2), as  
10                 so redesignated, the following:

11                 “(1) NOTIFICATION WITH RESPECT TO FED-  
12                 ERAL FACILITIES.—In the event of the release, loss,  
13                 or theft of an agent or toxin listed by the Secretary  
14                 pursuant to subsection (a)(1), or by the Secretary of  
15                 Agriculture pursuant to section 212(a)(1) of the Ag-  
16                 ricultural Bioterrorism Protection Act of 2002, from  
17                 or within a laboratory facility owned or operated by  
18                 the Department of Health and Human Services, or  
19                 other Federal laboratory facility subject to the re-  
20                 quirements of this section, the Secretary, in a man-  
21                 ner that does not compromise national security,  
22                 shall—

23                         “(A) not later than 72 hours after such  
24                         event is reported to the Secretary, notify the  
25                         Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on  
2 Energy and Commerce of the House of Rep-  
3 resentatives of such event, including—

4 “(i) the Federal laboratory facility in  
5 which such release, loss, or theft occurred;  
6 and

7 “(ii) the circumstances of such re-  
8 lease, loss, or theft; and

9 “(B) not later than 14 days after such no-  
10 tification, update such Committees on—

11 “(i) any actions taken or planned by  
12 the Secretary to mitigate any potential  
13 threat such release, loss, or theft may pose  
14 to public health and safety; and

15 “(ii) any actions taken or planned by  
16 the Secretary to review the circumstances  
17 of such release, loss, or theft, and prevent  
18 similar events.”; and

19 (C) by amending paragraph (2), as so re-  
20 designated, to read as follows:

21 “(2) ANNUAL REPORT.—The Secretary shall  
22 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 on an annual basis a report—



1           “(A) summarizing the number and nature  
2 of notifications received under subsection (e)(8)  
3 (relating to theft or loss) and subsection (j) (re-  
4 lating to releases), during the preceding fiscal  
5 year;

6           “(B) describing actions taken by the Sec-  
7 retary to address such incidents, such as any  
8 corrective action plans required and steps taken  
9 to promote adherence to, and compliance with,  
10 safety and security best practices, standards,  
11 and regulations; and

12           “(C) describing any gaps, challenges, or  
13 limitations with respect to ensuring that such  
14 safety and security practices are consistently  
15 applied and adhered to, and actions taken to  
16 address such gaps, challenges, or limitations.”;  
17 and

18           (4) in subsection (m), by striking “fiscal years  
19 2002 through 2007” and inserting “fiscal years  
20 2023 through 2027”.

21 **SEC. 312. STRATEGY FOR FEDERAL HIGH-CONTAINMENT**  
22 **LABORATORIES.**

23           (a) STRATEGY FOR FEDERAL HIGH-CONTAINMENT  
24 LABORATORIES.—Not later than 1 year after the date of  
25 enactment of this Act, the Director of the Office of Science

1 and Technology Policy, in consultation with relevant Fed-  
2 eral agencies and departments, shall establish a strategy  
3 for the management, maintenance, and oversight of feder-  
4 ally-owned laboratory facilities capable of operating at  
5 Biosafety Level 3 or 4, including equivalent classification  
6 levels. Such strategy shall include—

7           (1) a description of the roles and responsibil-  
8           ities of relevant Federal departments and agencies  
9           with respect to the management, maintenance, and  
10          oversight of Biosafety Level 3 or 4 laboratory facili-  
11          ties;

12          (2) an assessment of the needs of the Federal  
13          Government with respect to Biosafety Level 3 or 4  
14          laboratory facilities;

15          (3) a summary of existing federally-owned Bio-  
16          safety Level 3 or 4 laboratory facility capacity;

17          (4) a summary of other Biosafety Level 3 or 4  
18          laboratory facility capacity established through Fed-  
19          eral funds;

20          (5) a description of how the capacity described  
21          in paragraphs (3) and (4) addresses the needs of the  
22          Federal Government, including—

23                (A) how relevant Federal departments and  
24                agencies coordinate to provide access to appro-

1           appropriate laboratory facilities to reduce unneces-  
2           sary duplication; and

3                   (B) any gaps in such capacity related to  
4           such needs;

5           (6) a summary of plans that are in place for  
6           the maintenance of such capacity, as applicable and  
7           appropriate, including processes for determining  
8           whether to maintain or expand such capacity, and a  
9           description of how the Federal Government will ad-  
10          dress rapid changes in the need for such capacity  
11          during a public health emergency; and

12           (7) a description of how the heads of relevant  
13          Federal departments and agencies will coordinate to  
14          ensure appropriate oversight of federally-owned lab-  
15          oratory facility capacity and leverage such capacity,  
16          as appropriate, to fulfill the needs of multiple Fed-  
17          eral departments and agencies in order to reduce un-  
18          necessary duplication and improve collaboration  
19          within the Federal Government.

20 **SEC. 313. NATIONAL SCIENCE ADVISORY BOARD FOR BIO-**  
21 **SECURITY.**

22           (a) IN GENERAL.—Part A of title IV of the Public  
23          Health Service Act (42 U.S.C. 281 et seq.) is amended  
24          by adding at the end the following:

1 **“SEC. 4040. NATIONAL SCIENCE ADVISORY BOARD FOR**  
2 **BIOSECURITY.**

3 “(a) ESTABLISHMENT.—The Secretary, acting  
4 through the Director of NIH, shall establish an advisory  
5 committee, to be known as the ‘National Science Advisory  
6 Board for Biosecurity’ (referred to in this section as the  
7 ‘Board’).

8 “(b) DUTIES.—

9 “(1) IN GENERAL.—The National Science Advi-  
10 sory Board for Biosecurity referred to in section 205  
11 of the Pandemic and All-Hazards Preparedness Act  
12 (Public Law 109–417) (referred to in this section as  
13 the ‘Board’) shall provide technical advice, guidance,  
14 or recommendations, to relevant Federal depart-  
15 ments and agencies related to biosafety and biosecu-  
16 rity oversight of biomedical research, including—

17 “(A) oversight of federally-conducted or  
18 federally-supported dual use biomedical re-  
19 search, such as the review of policies or frame-  
20 works used to assess and appropriately manage  
21 safety and security risks associated with such  
22 research, taking into consideration national se-  
23 curity concerns, the potential benefits of such  
24 research, considerations related to the research  
25 community, transparency, and public avail-

1 ability of information, and international re-  
2 search collaboration; and

3 “(B) continuing to carry out the activities  
4 required under section 205 of the Pandemic  
5 and All-Hazards Preparedness Act (Public Law  
6 109–417).

7 “(c) CONSIDERATIONS.—In carrying out the duties  
8 under subsection (b), the Board may consider strategies  
9 to improve the safety and security of biomedical research,  
10 including through—

11 “(1) leveraging or using new technologies and  
12 scientific advancements to reduce safety and security  
13 risks associated with such research and improve con-  
14 tainment of pathogens; and

15 “(2) outreach to, and education and training of,  
16 researchers, laboratory personnel, and other appro-  
17 priate individuals with respect to safety and security  
18 risks associated with such research and mitigation of  
19 such risks.

20 “(d) MEMBERSHIP.—The Board shall be composed of  
21 the following:

22 “(1) Non-voting, ex officio members, including  
23 the following:

24 “(A) At least one representative of each of  
25 the following:

1                   “(i) The Department of Health and  
2                   Human Services.

3                   “(ii) The Department of Defense.

4                   “(iii) The Department of Agriculture.

5                   “(iv) The Department of Homeland  
6                   Security.

7                   “(v) The Department of Energy.

8                   “(vi) The Department of State.

9                   “(vii) The Office of Science and Tech-  
10                  nology Policy.

11                  “(viii) The Office of the Director of  
12                  National Intelligence.

13                  “(B) Representatives of such other Federal  
14                  departments or agencies as the Secretary deter-  
15                  mines appropriate to carry out the requirements  
16                  of this section.

17                  “(2) Individuals, appointed by the Secretary,  
18                  with expertise in biology, infectious diseases, public  
19                  health, ethics, national security, and other fields, as  
20                  the Secretary determines appropriate, who shall  
21                  serve as voting members.”.

22                  (b) ORDERLY TRANSITION.—The Secretary of  
23                  Health and Human Services shall take such steps as are  
24                  necessary to provide for the orderly transition to the au-  
25                  thority of the National Science Advisory Board for Bio-

1 security established under section 404O of the Public  
2 Health Service Act, as added by subsection (a), from any  
3 authority of the Board described in section 205 of the  
4 Pandemic and All-Hazards Preparedness Act (Public Law  
5 109–417), as in effect on the day before the date of enact-  
6 ment of this Act.

7 (c) APPLICATION.—The requirements under section  
8 404O of the Public Health Service Act, as added by sub-  
9 section (a), related to the mission, activities, or functions  
10 of the National Science Advisory Board for Biosecurity  
11 shall not apply until the completion of any work under-  
12 taken by such Board before the date of enactment of this  
13 Act.

14 **SEC. 314. RESEARCH TO IMPROVE BIOSAFETY.**

15 (a) IN GENERAL.—The Secretary of Health and  
16 Human Services (referred to in this section as the “Sec-  
17 retary”) shall, as appropriate, conduct or support research  
18 to improve the safe conduct of biomedical research activi-  
19 ties involving pathogens of pandemic potential or biologi-  
20 cal agents or toxins listed pursuant to section 351A(a)(1)  
21 of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

22 (b) REPORT.—Not later than 5 years after the date  
23 of enactment of this Act, the Secretary shall prepare and  
24 submit a report to the Committee on Health, Education,  
25 Labor, and Pensions of the Senate and the Committee on

1 Energy and Commerce of the House of Representatives  
2 regarding an overview of any research conducted or sup-  
3 ported under this section, any relevant findings, and steps  
4 the Secretary is taking to disseminate any such findings  
5 to support the reduction of risks associated with bio-  
6 medical research involving pathogens of pandemic poten-  
7 tial or biological agents or toxins listed pursuant to section  
8 351A(a)(1) of the Public Health Service Act (42 U.S.C.  
9 262a(a)(1)).

10 **SEC. 315. FEDERALLY-FUNDED RESEARCH WITH EN-**  
11 **HANCED PATHOGENS OF PANDEMIC POTEN-**  
12 **TIAL.**

13 (a) REVIEW AND OVERSIGHT OF ENHANCED PATHO-  
14 GENS OF PANDEMIC POTENTIAL.—

15 (1) IN GENERAL.—The Director of the Office of  
16 Science and Technology Policy (referred to in this  
17 section as the “Director”), in consultation with the  
18 heads of relevant Federal departments and agencies,  
19 shall—

20 (A) not later than 1 years after the date  
21 of enactment of this Act—

22 (i) continue or conduct a review of ex-  
23 isting Federal policies related to research  
24 proposed for Federal funding that may be  
25 reasonably anticipated to involve the cre-



1           ation, transfer, or use of pathogens of pan-  
2           demic potential; and

3                   (ii) establish or update a Federal pol-  
4           icy for the consistent review and oversight  
5           of such proposed research that appro-  
6           priately considers the risks associated with,  
7           and potential benefits of, such research;  
8           and

9                   (B) not less than every 4 years thereafter,  
10          review and update such policy, as necessary and  
11          appropriate, to ensure that such policy fully ac-  
12          counts for relevant research that may be rea-  
13          sonably anticipated to involve the creation,  
14          transfer, or use of enhanced pathogens of pan-  
15          demic potential, takes into consideration the  
16          benefits of such research, and supports the  
17          mitigation of related risks.

18           (2) REQUIREMENTS.—The policy established  
19          pursuant to paragraph (1) shall include—

20                   (A) a clear scope to support the consistent  
21          identification of research proposals subject to  
22          such policy by relevant Federal departments  
23          and agencies;

24                   (B) a framework for such reviews that ac-  
25          counts for safety, security, and ethical consider-

1           ations related to the creation, transfer, or use  
2           of enhanced pathogens of pandemic potential;

3           (C) measures to enhance the transparency  
4           and public availability of information related to  
5           such research activities in a manner that does  
6           not compromise national security, the safety  
7           and security of such research activities, or any  
8           identifiable, sensitive information of relevant in-  
9           dividuals; and

10          (D) consistent procedures across relevant  
11          Federal department and agencies to ensure  
12          that—

13               (i) proposed research that has been  
14               determined to have scientific and technical  
15               merit and may be subject to such policy is  
16               identified and referred for review;

17               (ii) subjected research activities con-  
18               ducted under an award, including activities  
19               undertaken by any subrecipients of such  
20               award, are monitored regularly throughout  
21               the project period to ensure compliance  
22               with such policy and the terms and condi-  
23               tions of such award; and

24               (iii) in the event that federally-funded  
25               research activities not subject to such pol-

1           icy produce unanticipated results related to  
2           the creation, transfer, or use of enhanced  
3           pathogens of pandemic potential, such re-  
4           search activities are identified and appro-  
5           priately reviewed under such policy.

6           (3) CLARIFICATION.—Reviews required pursu-  
7           ant to this section shall be in addition to any appli-  
8           cable requirements for research project applications  
9           required under the Public Health Service Act, in-  
10          cluding reviews required under section 492 of such  
11          Act (42 U.S.C. 289a), as applicable, or other appli-  
12          cable laws.

13          (b) IMPLEMENTATION.—

14           (1) IN GENERAL.—The Director shall direct all  
15           heads of relevant Federal departments and agencies  
16           to update, modernize, or promulgate applicable im-  
17           plementing regulations and guidance to implement  
18           the requirements of this section.

19           (2) UPDATES.—Consistent with the require-  
20           ments under subsection (a)(1)(B), the Director shall  
21           require all heads of relevant Federal departments  
22           and agencies to update such policies consistent with  
23           any changes to the policy established pursuant to  
24           subsection (a)(1).

1 **Subtitle C—Preventing Undue For-**  
2 **eign Influence in Biomedical**  
3 **Research**

4 **SEC. 321. FOREIGN TALENT PROGRAMS.**

5       The Secretary of Health and Human Services shall  
6 require disclosure of participation in foreign talent pro-  
7 grams, including the provision of copies of all grants, con-  
8 tracts, or other agreements related to such programs, and  
9 other supporting documentation related to such programs,  
10 as a condition of receipt of Federal extramural biomedical  
11 research funding awarded through the Department of  
12 Health and Human Services.

13 **SEC. 322. SECURING IDENTIFIABLE, SENSITIVE INFORMA-**  
14 **TION.**

15       (a) IN GENERAL.—The Secretary of Health and  
16 Human Services (referred to in this section as the “Sec-  
17 retary”), in consultation with the Director of National In-  
18 telligence, the Secretary of State, the Secretary of De-  
19 fense, and other national security experts, as appropriate,  
20 shall ensure that biomedical research supported or con-  
21 ducted by the National Institutes of Health and other rel-  
22 evant agencies and offices within the Department of  
23 Health and Human Services involving the sequencing of  
24 human genomic information, and collection, analysis, or  
25 storage of identifiable, sensitive information, as defined in

1 section 301(d)(4) of the Public Health Service Act (42  
2 U.S.C. 241(d)(4)), is conducted in a manner that appro-  
3 priately considers national security risks, including na-  
4 tional security implications related to potential misuse of  
5 such data. Not later than 1 year after the date of enact-  
6 ment of this Act, the Secretary shall ensure that the Na-  
7 tional Institutes of Health and other relevant agencies and  
8 offices within the Department of Health and Human Serv-  
9 ices, working with the heads of agencies and national secu-  
10 rity experts, including the Office of the National Security  
11 within the Department of Health and Human Services—

12           (1) develop a comprehensive framework for as-  
13           sessing and managing such national security risks  
14           that includes—

15                   (A) criteria for how and when to conduct  
16                   risk assessments for projects that may have na-  
17                   tional security implications;

18                   (B) security controls and training for re-  
19                   searchers or entities, including peer reviewers,  
20                   that manage or have access to such data; and

21                   (C) methods to incorporate risk-reduction  
22                   in the process for funding such projects that  
23                   may have national security implications;

1           (2) not later than 1 year after the risk frame-  
2 work is developed under paragraph (1), develop and  
3 implement controls to—

4           (A) ensure that researchers or entities that  
5 manage or have access to such data have com-  
6 plied with the requirements of paragraph (1)  
7 and ongoing requirements with such paragraph;  
8 and

9           (B) ensure that data access committees re-  
10 viewing data access requests for projects that  
11 may have national security risks, as appro-  
12 priate, include members with expertise in cur-  
13 rent and emerging national security threats, in  
14 order to make appropriate decisions related to  
15 access to such identifiable, sensitive informa-  
16 tion; and

17           (3) not later than 2 years after the risk frame-  
18 work is developed under paragraph (1), update data  
19 access and sharing policies related to human  
20 genomic data, as appropriate, based on current and  
21 emerging national security threats.

22           (b) CONGRESSIONAL BRIEFING.—Not later than 1  
23 year after the date of enactment of this Act, the Secretary  
24 shall provide a briefing to the Committee on Health, Edu-  
25 cation, Labor, and Pensions and the Select Committee on

1 Intelligence of the Senate and the Committee on Energy  
2 and Commerce and the Permanent Select Committee on  
3 Intelligence of the House of Representatives on the activi-  
4 ties required under subsection (a).

5 **SEC. 323. DUTIES OF THE DIRECTOR.**

6 Section 402(b) in the Public Health Service Act (42  
7 U.S.C. 282(b)), as amended by section 303, is further  
8 amended by inserting after paragraph (26) (as added by  
9 section 303) the following:

10 “(27) shall consult with the Director of the Of-  
11 fice of National Security within the Department of  
12 Health and Human Services, the Assistant Secretary  
13 for Preparedness and Response, the Director of Na-  
14 tional Intelligence, the Director of the Federal Bu-  
15 reau of Investigation, and the heads of other appro-  
16 priate agencies on a regular basis, regarding bio-  
17 medical research conducted or supported by the Na-  
18 tional Institutes of Health that may affect or be af-  
19 fected by matters of national security;

20 “(28) shall ensure that recipients of awards  
21 from the National Institutes of Health, and, as ap-  
22 propriate and practicable, entities collaborating with  
23 such recipients, have in place and are adhering to  
24 appropriate technology practices and policies for the  
25 security of identifiable, sensitive information, includ-

1 ing information collected, stored, or analyzed by do-  
2 mestic and non-domestic entities; and

3 “(29) shall ensure that recipients of awards  
4 from the National Institutes of Health are in compli-  
5 ance with the terms and conditions of such award,  
6 which may include activities to support awareness of,  
7 and compliance with, such terms and conditions by  
8 any subrecipients of the award.”.

9 **SEC. 324. PROTECTING AMERICA’S BIOMEDICAL RESEARCH**  
10 **ENTERPRISE.**

11 (a) IN GENERAL.—The Secretary of Health and  
12 Human Services (referred to in this section as the “Sec-  
13 retary”), in collaboration with Assistant to the President  
14 for National Security Affairs, the Director of National In-  
15 telligence, the Director of the Federal Bureau of Inves-  
16 tigation, and the heads of other relevant departments and  
17 agencies, and in consultation with research institutions  
18 and research advocacy organizations or other relevant ex-  
19 perts, as appropriate, shall—

20 (1) identify ways to improve the protection of  
21 intellectual property and other proprietary informa-  
22 tion, as well as identifiable, sensitive information of  
23 participants in biomedical research and development,  
24 from national security risks and other applicable  
25 threats, including the identification of gaps in poli-



1       cies and procedures in such areas related to bio-  
2       medical research and development supported by the  
3       Department of Health and Human Services and bio-  
4       medical research supported by other agencies as ap-  
5       plicable, and make recommendations to institutions  
6       of higher education or other entities that have tradi-  
7       tionally received Federal funding for biomedical re-  
8       search to protect such information;

9               (2) identify or develop strategies to prevent,  
10       mitigate, and address national security threats in  
11       biomedical research and development supported by  
12       the Federal Government, including such threats as-  
13       sociated with foreign talent programs, by countries  
14       seeking to exploit United States technology and  
15       other proprietary information as it relates to such  
16       biomedical research and development;

17               (3) identify national security risks and potential  
18       misuse of proprietary information, and identifiable,  
19       sensitive information of biomedical research partici-  
20       pants and other applicable risks, including with re-  
21       spect to peer review, and make recommendations for  
22       additional policies and procedures to protect such in-  
23       formation;

24               (4) develop a framework to identify areas of  
25       biomedical research and development supported by

1 the Federal Government that are emerging areas of  
2 interest for state actors and would compromise na-  
3 tional security if they were to be subjected to undue  
4 foreign influence; and

5 (5) regularly review recommendations or poli-  
6 cies developed under this section and make addi-  
7 tional recommendations or updates, as appropriate.

8 (b) REPORT TO PRESIDENT AND TO CONGRESS.—

9 Not later than 1 year after the date of enactment of this  
10 Act, the Secretary shall prepare and submit, in a manner  
11 that does not compromise national security, to the Presi-  
12 dent and the Committee on Health, Education, Labor, and  
13 Pensions and the Select Committee on Intelligence of the  
14 Senate, the Committee on Energy and Commerce and the  
15 Permanent Select Committee on Intelligence of the House  
16 of Representatives, and other congressional committees as  
17 appropriate, a report on the findings and recommenda-  
18 tions pursuant to subsection (a).

19 **SEC. 325. GAO STUDY.**

20 (a) IN GENERAL.—The Comptroller General of the  
21 United States (referred to in this section as the “Comp-  
22 troller General”) shall conduct a study to assess the extent  
23 to which the Department of Health and Human Services  
24 (referred to in this section as the “Department”) utilizes  
25 or provides funding to entities that utilize such funds for

1 human genomic sequencing services or genetic services (as  
2 such term is defined in section 201(6) of the Genetic In-  
3 formation Nondiscrimination Act of 2008 (42 U.S.C.  
4 2000ff(6))) provided by entities, or subsidiaries of such  
5 entities, organized under the laws of a country or coun-  
6 tries of concern, in the estimation of the Director of Na-  
7 tional Intelligence or the head of another Federal depart-  
8 ment or agency, as appropriate.

9 (b) CONSIDERATIONS.—In carrying out the study  
10 under this section, the Comptroller General shall—

11 (1) consider—

12 (A) the extent to which the country or  
13 countries of concern could obtain human  
14 genomic information of citizens and residents of  
15 the United States from such entities that se-  
16 quence, analyze, collect, or store human  
17 genomic information and which the Director of  
18 National Intelligence or the head of another  
19 Federal department or agency reasonably an-  
20 ticipates may use such information in a manner  
21 inconsistent with the national security interests  
22 of the United States;

23 (B) whether the Department or recipient  
24 of such funds from the Department sought to  
25 provide funding to, or to use, domestic entities

1 with no such ties to the country or countries of  
2 concern for such purposes and any barriers to  
3 the use of domestic entities; and

4 (C) whether data use agreements, data se-  
5 curity measures, and other such measures taken  
6 by the Department or recipient of such funds  
7 from the Department are sufficient to protect  
8 the identifiable, sensitive information of the  
9 people of the United States and the national se-  
10 curity interests of the United States; and

11 (2) make recommendations to address any  
12 vulnerabilities to the United States national security  
13 identified, as appropriate.

14 (c) ESTIMATION.—In conducting the study under this  
15 section, the Comptroller General may, as appropriate and  
16 necessary to complete such study, investigate specific in-  
17 stances of such utilization of genetic sequencing services  
18 or genetic services, as described in subsection (a), to  
19 produce estimates of the potential prevalence of such utili-  
20 zation among entities in receipt of Departmental funds.

21 (d) REPORT.—Not later than 2 years after the date  
22 of enactment of this Act, the Comptroller General shall  
23 submit a report on the study under this section, in a man-  
24 ner that does not compromise national security, to the  
25 Committee on Health, Education, Labor, and Pensions

1 and the Select Committee on Intelligence of the Senate,  
2 and the Committee on Energy and Commerce and the Per-  
3 manent Select Committee on Intelligence of the House of  
4 Representatives. The report shall be submitted in unclassi-  
5 fied form, to the extent practicable, but may include a  
6 classified annex.

7 **SEC. 326. REPORT ON PROGRESS TO ADDRESS UNDUE FOR-**  
8 **EIGN INFLUENCE.**

9 Not later than 1 year after the date of enactment  
10 of this Act and annually thereafter, the Secretary of  
11 Health and Human Services shall prepare and submit to  
12 the Committee on Health, Education, Labor, and Pen-  
13 sions of the Senate and the Committee on Energy and  
14 Commerce in the House of Representatives, in a manner  
15 that does not compromise national security, a report on  
16 actions taken by such Secretary—

17 (1) to address cases of noncompliance with dis-  
18 closure requirements or research misconduct related  
19 to foreign influence, including—

20 (A) the number of potential noncompliance  
21 cases investigated by the National Institutes of  
22 Health or reported to the National Institutes of  
23 Health by a research institution, including re-  
24 lating to undisclosed research support, undis-

1 closed conflicts of interest or other conflicts of  
 2 commitment, and peer review violations;

3 (B) the number of cases referred to the  
 4 Office of Inspector General of the Department  
 5 of Health and Human Services, the Office of  
 6 National Security of the Department of Health  
 7 and Human Services, the Federal Bureau of In-  
 8 vestigation, or other law enforcement agencies;

9 (C) a description of enforcement actions  
 10 taken for noncompliance related to undue for-  
 11 eign influence; and

12 (D) any other relevant information; and

13 (2) to prevent, address, and mitigate instances  
 14 of noncompliance with disclosure requirements or re-  
 15 search misconduct related to foreign influence.

16 **TITLE IV—MODERNIZING AND**  
 17 **STRENGTHENING THE SUP-**  
 18 **PLY CHAIN FOR VITAL MED-**  
 19 **ICAL PRODUCTS**

20 **SEC. 401. WARM BASE MANUFACTURING CAPACITY FOR**  
 21 **MEDICAL COUNTERMEASURES.**

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

24 (1) in subsection (a)(6)(B)—

1 (A) by redesignating clauses (iv) and (v) as  
2 clauses (v) and (vi), respectively;

3 (B) by inserting after clause (iii), the fol-  
4 lowing:

5 “(iv) activities to support, maintain,  
6 and improve domestic manufacturing surge  
7 capacity and capabilities, as appropriate,  
8 including through the utilization of ad-  
9 vanced manufacturing and platform tech-  
10 nologies, to increase the availability of  
11 products that are or may become qualified  
12 countermeasures or qualified pandemic or  
13 epidemic products;” and

14 (C) in clause (vi) (as so redesignated), by  
15 inserting “manufacturing,” after “improve-  
16 ment,”;

17 (2) in subsection (b)—

18 (A) in the first sentence of paragraph (1),  
19 by inserting “support for domestic manufac-  
20 turing surge capacity and capabilities,” after  
21 “initiatives for innovation,”; and

22 (B) in paragraph (2)—

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

1                   (ii) by redesignating subparagraph  
2                   (C) as subparagraph (D); and

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

5                   “(C) activities to support, maintain, and  
6                   improve domestic manufacturing surge capacity  
7                   and capabilities, as appropriate, including  
8                   through the utilization of advanced manufac-  
9                   turing and platform technologies, to increase  
10                  the availability of products that are or may be-  
11                  come qualified countermeasures or qualified  
12                  pandemic or epidemic products; and”;

13                  (3) in subsection (c)—

14                  (A) in paragraph (2)(B), by inserting be-  
15                  fore the semicolon “, including through the es-  
16                  tablishment and maintenance of domestic man-  
17                  ufacturing surge capacity and capabilities, con-  
18                  sistent with subsection (a)(6)(B)(iv)”;

19                  (B) in paragraph (4)—

20                  (i) in subparagraph (A)—

21                          (I) in clause (i)—

22                                  (aa) in subclause (I), by  
23                                  striking “and” at the end; and

24                                  (bb) by adding at the end  
25                                  the following:



1           “(III) facilitating such commu-  
2           nication, as appropriate, regarding  
3           manufacturing surge capacity and ca-  
4           pabilities with respect to qualified  
5           countermeasures and qualified pan-  
6           demic or epidemic products to prepare  
7           for, or respond to, a public health  
8           emergency or potential public health  
9           emergency; and

10           “(IV) facilitating such commu-  
11           nication, as appropriate and in a man-  
12           ner that does not compromise national  
13           security, with respect to potential eli-  
14           gibility for the material threat medical  
15           countermeasure priority review vouch-  
16           er program under section 565A of the  
17           Federal Food, Drug, and Cosmetic  
18           Act;”;

19           (II) in clause (ii)(III), by striking  
20           “and” at the end;

21           (III) by redesignating clause (iii)  
22           as clause (iv); and

23           (IV) by inserting after clause (ii),  
24           the following:

1           “(iii) communicate regularly with enti-  
2 ties in receipt of an award pursuant to  
3 subparagraph (B)(v), and facilitate com-  
4 munication between such entities and other  
5 entities in receipt of an award pursuant to  
6 subparagraph (B)(iv), as appropriate, for  
7 purposes of planning and response regard-  
8 ing the availability of countermeasures and  
9 the maintenance of domestic manufac-  
10 turing surge capacity and capabilities, in-  
11 cluding any planned uses of such capacity  
12 and capabilities in the near- and mid-term,  
13 and identification of any significant chal-  
14 lenges related to the long-term mainte-  
15 nance of such capacity and capabilities;  
16 and”;

17           (ii) in subparagraph (B)—

18           (I) in clause (iii), by striking  
19 “and” at the end;

20           (II) in clause (iv), by striking the  
21 period and inserting “; and”; and

22           (III) by adding at the end the  
23 following:

24           “(v) award contracts, grants, and co-  
25 operative agreements and enter into other

1 transactions to support, maintain, and im-  
2 prove domestic manufacturing surge capac-  
3 ity and capabilities, including through sup-  
4 porting flexible or advanced manufac-  
5 turing, to ensure that additional capacity  
6 is available to rapidly manufacture prod-  
7 ucts that are or may become qualified  
8 countermeasures or qualified pandemic or  
9 epidemic products in the event of a public  
10 health emergency declaration or significant  
11 potential for a public health emergency.”;

12 (iii) in subparagraph (C)—

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

15 (II) in clause (ii), by striking the  
16 period at the end and inserting “;  
17 and”;

18 (III) by adding at the end the  
19 following:

20 “(iii) consult with the Commissioner  
21 of Food and Drugs, pursuant to section  
22 565(b)(2) of the Federal Food, Drug, and  
23 Cosmetic Act, to ensure that facilities per-  
24 forming manufacturing, pursuant to an  
25 award under subparagraph (B)(v), are in

1 compliance with applicable requirements  
2 under such Act and this Act, as appro-  
3 priate, including current good manufac-  
4 turing practice pursuant to section  
5 501(a)(2)(B) of the Food, Drug, and Cos-  
6 metic Act; and”;

7 (iv) in subparagraph (D)(i), by insert-  
8 ing “, including to improve manufacturing  
9 capacities and capabilities for medical  
10 countermeasures” before the semicolon;

11 (v) in subparagraph (E)(ix), by strik-  
12 ing “2023” and inserting “2028”; and

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

15 “(G) ANNUAL REPORTS BY AWARD RECIPI-  
16 ENTS.—As a condition of receiving an award  
17 under subparagraph (B)(v), a recipient shall de-  
18 velop and submit to the Secretary annual re-  
19 ports related to the maintenance of such capac-  
20 ity and capabilities, including ensuring that  
21 such capacity and capabilities are able to sup-  
22 port the rapid manufacture of countermeasures  
23 as required by the Secretary.”; and

24 (C) in paragraph (5), by adding at the end  
25 the following:

1           “(H) SUPPORTING WARM-BASE AND SURGE  
2           CAPACITY AND CAPABILITIES.—Pursuant to an  
3           award under subparagraph (B)(v), the Sec-  
4           retary may make payments for activities nec-  
5           essary to maintain domestic manufacturing  
6           surge capacity and capabilities supported under  
7           such award to ensure that such capacity and  
8           capabilities are able to support the rapid manu-  
9           facture of countermeasures as required by the  
10          Secretary to prepare for, or respond to, an ex-  
11          isting or potential public health emergency or  
12          otherwise address threats that pose a signifi-  
13          cant level of risk to national security. The Sec-  
14          retary may support the utilization of such ca-  
15          pacity and capabilities under awards for coun-  
16          termeasure and product advanced research and  
17          development, as appropriate, to provide for the  
18          maintenance of such capacity and capabilities.”;  
19          and  
20          (4) in subsection (f)—

21                 (A) in paragraph (1), by striking “Not  
22                 later than 180 days after the date of enactment  
23                 of this subsection” and inserting “Not later  
24                 than 180 days after the date of enactment of  
25                 the PREVENT Pandemics Act”;

1 (B) in paragraph (2)—

2 (i) in the matter preceding subpara-  
3 graph (A), by striking “this subsection”  
4 and inserting “the PREVENT Pandemics  
5 Act”;

6 (ii) in subparagraph (B), by striking  
7 “and” at the end; and

8 (iii) in subparagraph (C), by striking  
9 the period and inserting “; and”; and  
10 (C) by adding at the end the following:

11 “(D) plans for the near-, mid-, and long-  
12 term sustainment of manufacturing activities  
13 carried out under this section, including such  
14 activities pursuant to subsection (c)(5)(H), spe-  
15 cific actions to regularly assess the ability of re-  
16 cipients of an award under subsection  
17 (c)(4)(B)(v) to rapidly manufacture counter-  
18 measures as required by the Secretary, and rec-  
19 ommendations to address challenges, if any, re-  
20 lated to such activities.”.

21 **SEC. 402. SUPPLY CHAIN CONSIDERATIONS FOR THE STRA-**  
22 **TEGIC NATIONAL STOCKPILE.**

23 Subclause (II) of section 319F–2(a)(2)(B)(i) of the  
24 Public Health Service Act (42 U.S.C. 247d–  
25 6b(a)(2)(B)(i)) is amended to read as follows:

1 “(II) planning considerations for  
2 appropriate manufacturing capacity  
3 and capability to meet the goals of  
4 such additions or modifications (with-  
5 out disclosing proprietary informa-  
6 tion), including—

7 “(aa) consideration of the  
8 effect such additions or modifica-  
9 tions may have on the availability  
10 of such products and ancillary  
11 medical supplies on the health  
12 care system; and

13 “(bb) an assessment of the  
14 current supply chain for such  
15 products, including information  
16 on supply chain redundancies,  
17 any known domestic manufac-  
18 turing capacity for such prod-  
19 ucts, and any related  
20 vulnerabilities;”.

21 **SEC. 403. STRATEGIC NATIONAL STOCKPILE EQUIPMENT**  
22 **MAINTENANCE.**

23 Subparagraph (D) of section 319F-2(a)(3) of the  
24 Public Health Service Act (42 U.S.C. 247d-6b(a)(3)) is  
25 amended to read as follows:

1           “(D) review and revise, as appropriate, the  
2 contents of the stockpile on a regular basis to  
3 ensure that—

4                   “(i) emerging threats, advanced tech-  
5 nologies, and new countermeasures are  
6 adequately considered;

7                   “(ii) the potential depletion of coun-  
8 termeasures currently in the stockpile is  
9 identified and appropriately addressed, in-  
10 cluding through necessary replenishment;  
11 and

12                   “(iii) such contents are in working  
13 condition or usable, as applicable, and are  
14 ready for deployment, which may include  
15 conducting maintenance services on such  
16 contents of the stockpile and disposing of  
17 such contents that are no longer in work-  
18 ing condition, or usable, as applicable;”.

19 **SEC. 404. IMPROVING TRANSPARENCY AND PREDICT-**  
20 **ABILITY OF PROCESSES OF THE STRATEGIC**  
21 **NATIONAL STOCKPILE.**

22           (a) **GUIDANCE.**—Not later than 60 days after the  
23 date of enactment of this Act, the Secretary of Health and  
24 Human Services (referred to in this section as the “Sec-  
25 retary”) shall issue guidance describing the processes by



1 which the Secretary deploys the contents of the Strategic  
2 National Stockpile under section 319F–2(a) of the Public  
3 Health Service Act (42 U.S.C. 247d–6b(a)), or otherwise  
4 distributes medical countermeasures, as applicable, to  
5 States, territories, Indian Tribes and Tribal organizations  
6 (as such terms are defined under section 4 of the Indian  
7 Self-Determination and Education Assistance Act), and  
8 other applicable entities. Such guidance shall include in-  
9 formation related to processes by which to request access  
10 to the contents of the Strategic National Stockpile, factors  
11 considered by the Secretary when making deployment or  
12 distribution decisions, and processes and points of contact  
13 through which entities may contact the Secretary to ad-  
14 dress any issues related to products requested or received  
15 by such entity from the stockpile, and on other relevant  
16 topics.

17 (b) ANNUAL MEETINGS.—Section 319F–2(a)(3) of  
18 the Public Health Service Act (42 U.S.C. 247d–6b(a)(3))  
19 is amended—

20 (1) in subparagraph (I), by striking “and” at  
21 the end;

22 (2) in subparagraph (J), by striking the period  
23 at the end and inserting “; and”; and

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

1           “(K) convene meetings, not less than once  
2 per year, with representatives from State, local,  
3 and Tribal health departments or officials, rel-  
4 evant industries, other Federal agencies, and  
5 other appropriate stakeholders, in a manner  
6 that does not compromise national security, to  
7 coordinate and share information related to  
8 maintenance and use of the stockpile, including  
9 a description of future countermeasure needs  
10 and additions, modifications, and replenish-  
11 ments of the contents of the stockpile, and con-  
12 siderations related to the manufacturing and  
13 procurement of products consistent with the re-  
14 quirements of the Buy American Act of 1933,  
15 as appropriate.”.

16 **SEC. 405. IMPROVING SUPPLY CHAIN FLEXIBILITY FOR THE**  
17 **STRATEGIC NATIONAL STOCKPILE.**

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

20           (1) in subsection (a)—

21           (A) in paragraph (3)(F), by striking “as  
22 required by the Secretary of Homeland Secu-  
23 rity” and inserting “at the discretion of the  
24 Secretary, in consultation with, or at the re-  
25 quest of, the Secretary of Homeland Security,”;

1 (B) by redesignating paragraphs (5) and  
2 (6) as paragraphs (6) and (7), respectively;

3 (C) by inserting after paragraph (4) the  
4 following:

5 “(5) VENDOR-MANAGED INVENTORY AND  
6 WARM-BASE SURGE CAPACITY.—

7 “(A) IN GENERAL.—For the purposes of  
8 maintaining the stockpile under paragraph (1)  
9 and carrying out procedures under paragraph  
10 (3), the Secretary may enter into contracts or  
11 cooperative agreements with vendors, which  
12 may include manufacturers or distributors of  
13 medical products, with respect to medical prod-  
14 ucts intended to be delivered to the ownership  
15 of the Federal Government. Each such contract  
16 or cooperative agreement shall be subject to  
17 such terms and conditions as the Secretary may  
18 specify, including terms and conditions with re-  
19 spect to—

20 “(i) procurement, maintenance, stor-  
21 age, and delivery of reserve amounts of  
22 products under such contract or coopera-  
23 tive agreement, which may consider, as ap-  
24 propriate, costs of transporting and han-  
25 dling such products; and

1           “(ii) maintenance of domestic manu-  
2           facturing capacity and capabilities of such  
3           products to ensure additional reserved pro-  
4           duction capacity and capabilities are avail-  
5           able, and that such capacity and capabili-  
6           ties are able to support the rapid manufac-  
7           ture, purchase, storage, and delivery of  
8           such products, as required by the Sec-  
9           retary to prepare for, or respond to, an ex-  
10          isting or potential public health emergency.

11          “(B) REPORT.—Not later than 2 years  
12          after the date of enactment of the PREVENT  
13          Pandemics Act, and annually thereafter, the  
14          Secretary shall submit to the Committee on  
15          Health, Education, Labor, and Pensions of the  
16          Senate and the Committee on Energy and Com-  
17          merce of the House of Representatives a report  
18          on any contracts or cooperative agreements en-  
19          tered into under subparagraph (A) for purposes  
20          of establishing and maintaining vendor-man-  
21          aged inventory or reserve manufacturing capac-  
22          ity and capabilities for products intended for  
23          the stockpile, including a description of—

24                 “(i) the amount of each award;

25                 “(ii) the recipient of each award;

1 “(iii) the product or products covered  
2 through each award; and

3 “(iv) how the Secretary works with  
4 each recipient to ensure situational aware-  
5 ness related to the manufacturing capacity  
6 for, or inventory of, such products and co-  
7 ordinates the distribution and deployment  
8 of such products, as appropriate and appli-  
9 cable.”; and

10 (D) in subparagraph (A) of paragraph (6),  
11 as so redesignated—

12 (i) in clause (viii), by striking “; and”  
13 and inserting a semicolon;

14 (ii) in clause (ix), by striking the pe-  
15 riod and inserting “; and”; and

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

18 “(x) with respect to reports issued in  
19 2027 or any subsequent year, an assess-  
20 ment of selected contracts or cooperative  
21 agreements entered into pursuant to para-  
22 graph (5).”; and

23 (2) in subsection (c)(2)(C), by striking “on an  
24 annual basis” and inserting “not later than March  
25 15 of each year”.

1 (b) AUTHORIZATION OF APPROPRIATIONS.—Section  
2 319F–2(f)(1) of the Public Health Service Act (42 U.S.C.  
3 247d–6b(f)(1)) is amended by striking “\$610,000,000 for  
4 each of fiscal years 2019 through 2023” and inserting  
5 “\$610,000,000 for each of fiscal year 2019 through 2021,  
6 and \$750,000,000 for each of fiscal years 2022 and  
7 2023”.

8 **SEC. 406. REIMBURSEMENT FOR CERTAIN SUPPLIES.**

9 Paragraph (7) of section 319F–2(a) of the Public  
10 Health Service Act (42 U.S.C. 247d–6b(a)), as so redesign-  
11 nated by section 405(a)(1)(B), is amended to read as fol-  
12 lows:

13 “(7) REIMBURSEMENT FOR CERTAIN SUP-  
14 PLIES.—

15 “(A) IN GENERAL.—The Secretary may, at  
16 appropriate intervals, make available for pur-  
17 chase excess contents procured for, and main-  
18 tained within, the stockpile under paragraph (1)  
19 to any Federal agency or State, local, or Tribal  
20 government. The Secretary shall make such  
21 contents available for purchase only if—

22 “(i) such contents are in excess of  
23 what is required for appropriate mainte-  
24 nance of such stockpile;

1           “(ii) the Secretary determines that  
2           the costs for maintaining such excess con-  
3           tents are not appropriate to expend to  
4           meet the needs of the stockpile; and

5           “(iii) the Secretary determines that  
6           such action does not compromise national  
7           security and is in the national interest.

8           “(B) REIMBURSEMENT AND COLLEC-  
9           TION.—The Secretary may require reimburse-  
10          ment for contents that are made available  
11          under subparagraph (A), in an amount that re-  
12          flects the cost of acquiring and maintaining  
13          such contents and the costs incurred to make  
14          available such contents in the time and manner  
15          specified by the Secretary. Amounts collected  
16          under this subsection shall be credited to the  
17          appropriations account or fund that incurred  
18          the costs to procure such contents, and shall re-  
19          main available, without further appropriation,  
20          until expended, for the purposes of the appro-  
21          priation account or fund so credited.

22          “(C) RULE OF CONSTRUCTION.—This  
23          paragraph shall not be construed to preclude  
24          transfers of contents in the stockpile under  
25          other authorities.

1           “(D) REPORT.—Not later than 2 years  
2           after the date of enactment of the PREVENT  
3           Pandemics Act, and annually thereafter, the  
4           Secretary shall submit to the Committee on  
5           Health, Education, Labor, and Pensions and  
6           the Committee on Appropriations of the Senate  
7           and the Committee on Energy and Commerce  
8           and the Committee on Appropriations of the  
9           House of Representatives a report on the use of  
10          the authority provided under this paragraph, in-  
11          cluding details of each action taken pursuant to  
12          this paragraph, the account or fund to which  
13          any collected amounts have been credited, and  
14          how the Secretary has used such amounts.

15           “(E) SUNSET.—The authority under this  
16          paragraph shall terminate on September 30,  
17          2025.”.

18 **SEC. 407. ACTION REPORTING ON STOCKPILE DEPLETION.**

19          Section 319 of the Public Health Service Act (42  
20          U.S.C. 247d), as amended by section 223, is further  
21          amended by adding at the end the following:

22           “(h) STOCKPILE DEPLETION REPORTING.—The Sec-  
23          retary shall, not later than 30 days after the deployment  
24          of contents of the Strategic National Stockpile under sec-  
25          tion 319F–2(a) to respond to a public health emergency



1 declared by the Secretary under this section or an emer-  
2 gency or major disaster declared by the President under  
3 the Robert T. Stafford Disaster Relief and Emergency As-  
4 sistance Act, and every 30 days thereafter until the expira-  
5 tion or termination of such public health emergency, emer-  
6 gency, or major disaster, submit a report to the Com-  
7 mittee on Health, Education, Labor, and Pensions and the  
8 Committee on Appropriations of the Senate and the Com-  
9 mittee on Energy and Commerce and the Committee on  
10 Appropriations of the House of Representatives on—

11           “(1) the deployment of the contents of the  
12 stockpile in response to State, local, and Tribal re-  
13 quests;

14           “(2) the amount of such products that remain  
15 within the stockpile following such deployment; and

16           “(3) plans to replenish such products, as appro-  
17 priate, including related timeframes and any barriers  
18 or limitations to replenishment.”.

19 **SEC. 408. PROVISION OF MEDICAL COUNTERMEASURES TO**  
20 **INDIAN PROGRAMS AND FACILITIES.**

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

24           (1) in subparagraph (C), by striking “and  
25 local” and inserting “local, and Tribal”; and

1           (2) in subparagraph ( J), by striking “and  
2           local” and inserting “local, and Tribal”.

3           (b) DISTRIBUTION OF MEDICAL COUNTERMEASURES  
4 TO INDIAN TRIBES.—Title III of the Public Health Serv-  
5 ice Act (42 U.S.C. 241 et seq.) is amended by inserting  
6 after section 319F–4 the following:

7           **“SEC. 319F-5. PROVISION OF MEDICAL COUNTERMEASURES**  
8                                   **TO INDIAN PROGRAMS AND FACILITIES.**

9           “*In the event that the Secretary deploys the contents*  
10 *of the Strategic National Stockpile under section 319F–*  
11 *2(a), or otherwise distributes medical countermeasures to*  
12 *States to respond to a public health emergency declared*  
13 *by the Secretary under section 319, the Secretary shall,*  
14 *in consultation with the applicable States, make such con-*  
15 *tents or countermeasures directly available to Indian*  
16 *Tribes and Tribal organizations (as such terms are de-*  
17 *fin ed in section 4 of the Indian Self-Determination and*  
18 *Education Assistance Act (25 U.S.C. 5304), which may*  
19 *include through health programs or facilities operated by*  
20 *the Indian Health Service, that are affected by such public*  
21 *health emergency.”.*

22           **SEC. 409. GRANTS FOR STATE STRATEGIC STOCKPILES.**

23           (a) Section 319F–2 of the Public Health Service Act  
24 (42 U.S.C. 247d–6b) is amended by adding at the end  
25 the following:

1       “(i) PILOT PROGRAM TO SUPPORT STATE MEDICAL  
2 STOCKPILES.—

3               “(1) IN GENERAL.—The Secretary, in consulta-  
4 tion with the Assistant Secretary for Preparedness  
5 and Response and the Director of the Centers for  
6 Disease Control and Prevention, shall award grants  
7 or cooperative agreements to not fewer than 5  
8 States, or consortia of States, with consideration  
9 given to distribution among the geographical regions  
10 of the United States, to establish, expand, or main-  
11 tain a stockpile of appropriate drugs, vaccines and  
12 other biological products, medical devices, and other  
13 medical supplies determined by the State to be nec-  
14 essary to respond to a public health emergency de-  
15 clared by the Governor of a State or by the Sec-  
16 retary under section 319, or a major disaster or  
17 emergency declared by the President under section  
18 401 or 501, respectively, of the Robert T. Stafford  
19 Disaster Relief and Emergency Assistance Act, in  
20 order to support the preparedness goals described in  
21 paragraphs (2) through (6) and (8) of section  
22 2802(b).

23               “(2) REQUIREMENTS.—

24                       “(A) APPLICATION.—To be eligible to re-  
25 ceive an award under paragraph (1), an entity

1 shall prepare, in consultation with appropriate  
2 health care entities and health officials within  
3 the jurisdiction of such State or States, and  
4 submit to the Secretary an application that con-  
5 tains such information as the Secretary may re-  
6 quire, including—

7 “(i) a plan for such stockpile, con-  
8 sistent with paragraph (4), including a de-  
9 scription of the activities such entity will  
10 carry out under the agreement and an out-  
11 line of proposed expenses; and

12 “(ii) a description of how such entity  
13 will coordinate with relevant entities in re-  
14 ceipt of an award under section 319C–1 or  
15 319C–2 pursuant to paragraph (4), includ-  
16 ing through promoting alignment between  
17 the stockpile plan established pursuant to  
18 clause (i) and applicable plans that are es-  
19 tablished by such entity pursuant to sec-  
20 tion 319C–1 or 319C–2.

21 “(B) MATCHING FUNDS.—

22 “(i) Subject to clause (ii), the Sec-  
23 retary may not make an award under this  
24 subsection unless the applicant agrees,  
25 with respect to the costs to be incurred by

1 the applicant in carrying out the purpose  
2 described in this subsection, to make avail-  
3 able non-Federal contributions toward such  
4 costs in an amount equal to—

5 “(I) for each of fiscal years 2023  
6 and 2024, not less than \$1 for each  
7 \$20 of Federal funds provided in the  
8 award; and

9 “(II) for fiscal year 2025 and  
10 each fiscal year thereafter, not less  
11 than \$1 for each \$10 of Federal funds  
12 provided in the award.

13 “(ii) WAIVER.—The Secretary may,  
14 upon the request of a State, waive the re-  
15 quirement under clause (i), in whole or in  
16 part, if the Secretary determines that ex-  
17 traordinary economic conditions in the  
18 State in the fiscal year involved or in the  
19 previous fiscal year justify the waiver. A  
20 waiver provided by the Secretary under  
21 this subparagraph shall apply only to the  
22 fiscal year involved.

23 “(C) ADMINISTRATIVE EXPENSES.—Not  
24 more than 10 percent of amounts received by  
25 an entity pursuant to an award under this sub-

1 section may be used for administrative ex-  
2 penses.

3 “(3) LEAD ENTITY.—An entity in receipt of an  
4 award under paragraph (1) may designate a lead en-  
5 tity, which may be a public or private entity, as ap-  
6 propriate, to manage the stockpile at the direction of  
7 the State or consortium of States.

8 “(4) USE OF FUNDS.—An entity in receipt of  
9 an award under paragraph (1) shall use such funds  
10 to—

11 “(A) purchase, store, and maintain a  
12 stockpile of appropriate drugs, vaccines and  
13 other biological products, medical devices, and  
14 other medical supplies to be used during a pub-  
15 lic health emergency, major disaster, or emer-  
16 gency described in paragraph (1), in such num-  
17 bers, types, and amounts as the entity deter-  
18 mines necessary, consistent with such entity’s  
19 stockpile plan established pursuant to para-  
20 graph (2)(A)(i);

21 “(B) deploy the stockpile as required by  
22 the entity to respond to an actual or potential  
23 public health emergency, major disaster, or  
24 other emergency described in paragraph (1);

1           “(C) replenish and make necessary addi-  
2           tions or modifications to the contents of such  
3           stockpile, including to address potential deple-  
4           tion;

5           “(D) in consultation with Federal, State,  
6           and local officials, take into consideration the  
7           availability, deployment, dispensing, and admin-  
8           istration requirements of medical products with-  
9           in the stockpile;

10          “(E) ensure that procedures are followed  
11          for inventory management and accounting, and  
12          for the physical security of the stockpile, as ap-  
13          propriate;

14          “(F) review and revise, as appropriate, the  
15          contents of the stockpile on a regular basis to  
16          ensure that, to the extent practicable, new tech-  
17          nologies and medical products are considered;

18          “(G) carry out exercises, drills, and other  
19          training for purposes of stockpile deployment,  
20          dispensing, and administration of medical prod-  
21          ucts, and for purposes of assessing the capa-  
22          bility of such stockpile to address the medical  
23          supply needs of public health emergencies,  
24          major disasters, or other emergencies described  
25          in paragraph (1) of varying types and scales,

1           which may be conducted in accordance with re-  
2           quirements related to exercises, drills, and other  
3           training for recipients of awards under section  
4           319C–1 or 319C–2, as applicable; and

5           “(H) carry out other activities related to  
6           the State strategic stockpile as the entity deter-  
7           mines appropriate, to support State efforts to  
8           prepare for, and respond to, public health  
9           threats.

10          “(5) SUPPLEMENT NOT SUPPLANT.—Awards  
11          under paragraph (1) shall supplement, not supplant,  
12          the maintenance and use of the Strategic National  
13          Stockpile by the Secretary under subsection (a).

14          “(6) GUIDANCE FOR STATES.—Not later than  
15          180 days after the date of enactment of this sub-  
16          section, the Secretary, in consultation with States,  
17          health officials, and other relevant stakeholders, as  
18          appropriate, shall issue guidance, and update such  
19          guidance as appropriate, for States related to main-  
20          taining and replenishing a stockpile of medical prod-  
21          ucts, which may include strategies and best practices  
22          related to—

23                 “(A) types of medical products and med-  
24                 ical supplies that are critical to respond to pub-  
25                 lic health emergencies, and may be appropriate



1 for inclusion in a stockpile by States, with con-  
2 sideration of threats that require the large-scale  
3 and simultaneous deployment of stockpiles, in-  
4 cluding the stockpile maintained by the Sec-  
5 retary pursuant to subsection (a), and long-  
6 term public health and medical response needs;

7 “(B) appropriate management of the con-  
8 tents of a stockpile, including management by  
9 vendors of reserve amounts of medical products  
10 and supplies intended to be delivered to the  
11 ownership of the State and appropriate disposi-  
12 tion of excess products, as applicable; and

13 “(C) the procurement of medical products  
14 and medical supplies consistent with the Buy  
15 American Act of 1933.

16 “(7) TECHNICAL ASSISTANCE.—The Secretary  
17 shall provide assistance to States, including technical  
18 assistance, as appropriate, in establishing, maintain-  
19 ing, improving, and utilizing a medical stockpile, in-  
20 cluding appropriate inventory management and dis-  
21 position of products.

22 “(8) REPORTING.—

23 “(A) STATE REPORTS.—Each entity re-  
24 ceiving an award under paragraph (1) shall up-  
25 date, as appropriate, the plan established pur-

1           suant to paragraph (2)(A)(i) and submit to the  
2           Secretary an annual report on implementation  
3           of such plan, including any changes to the con-  
4           tents of the stockpile supported under such  
5           award. The Secretary shall use information ob-  
6           tained from such reports to inform the mainte-  
7           nance and management of the Strategic Na-  
8           tional Stockpile pursuant to subsection (a).

9           “(B) REPORTS TO CONGRESS.—Not later  
10          than 1 year after the initial issuance of awards  
11          pursuant to paragraph (1), and annually there-  
12          after for the duration of the program estab-  
13          lished under this subsection, the Secretary shall  
14          submit to the Committee on Health, Education,  
15          Labor, and Pensions of the Senate and the  
16          Committee on Energy and Commerce of the  
17          House of Representatives a report on such pro-  
18          gram, including—

19                 “(i) Federal and State expenditures to  
20                 support stockpiles under such program;

21                 “(ii) activities conducted pursuant to  
22                 paragraph (4); and

23                 “(iii) any additional information from  
24                 the States that the Secretary determines  
25                 relevant.

1           “(9) AUTHORIZATION OF APPROPRIATIONS.—

2           To carry out this subsection, there is authorized to  
3           be appropriated such sums as may be necessary for  
4           each of fiscal years 2023 through 2028.”.

5           (b) GAO REPORT.—Not later than 3 years after the  
6           date on which awards are first issued pursuant to sub-  
7           section (i)(1) of section 319F–2 of the Public Health Serv-  
8           ice Act (42 U.S.C. 247d–6b), as added by subsection (a),  
9           the Comptroller General of the United States shall submit  
10          to the Committee on Health, Education, Labor, and Pen-  
11          sions of the Senate and the Committee on Energy and  
12          Commerce of the House of Representatives a report on  
13          the State stockpiles established or maintained pursuant to  
14          this section. Such report shall include an assessment of—

15                (1) coordination and communication between  
16                the Secretary of Health and Human Services and  
17                entities in receipt of an award under this section, or  
18                a lead entity designated by such entity;

19                (2) technical assistance provided by the Sec-  
20                retary of Health and Human Services to such enti-  
21                ties; and

22                (3) the impact of such stockpiles on the ability  
23                of the State to prepare for and respond to a public  
24                health emergency, major disaster, or other emer-  
25                gency described in subsection (i)(1) of section 319F–

1 2 of the Public Health Service Act (42 U.S.C. 247d–  
 2 6b), as added by subsection (a), including the avail-  
 3 ability and distribution of items from such State  
 4 stockpile to health care entities and other applicable  
 5 entities.

6 **TITLE V—ENHANCING DEVELOP-**  
 7 **MENT AND COMBATING**  
 8 **SHORTAGES OF MEDICAL**  
 9 **PRODUCTS**

10 **Subtitle A—Development and**  
 11 **Review**

12 **SEC. 501. ADVANCING QUALIFIED INFECTIOUS DISEASE**  
 13 **PRODUCT INNOVATION.**

14 (a) IN GENERAL.—Section 505E of the Federal  
 15 Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amend-  
 16 ed—

17 (1) in subsection (c)—

18 (A) in paragraph (2), by striking “; or”  
 19 and inserting “;”;

20 (B) in paragraph (3), by striking the pe-  
 21 riod and inserting “; or”; and

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

23 “(4) an application pursuant to section 351(a)  
 24 of the Public Health Service Act.”;

1           (2) in subsection (d)(1), by inserting “of this  
2       Act or section 351(a) of the Public Health Service  
3       Act” after “section 505(b)”; and

4           (3) by amending subsection (g) to read as fol-  
5       lows:

6       “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—  
7       The term ‘qualified infectious disease product’ means a  
8       drug, including an antibacterial or antifungal drug or a  
9       biological product, for human use that—

10           “(1) acts directly on bacteria or fungi or on  
11       substances produced by such bacteria or fungi; and

12           “(2) is intended to treat a serious or life-threat-  
13       ening infection, including such an infection caused  
14       by—

15           “(A) an antibacterial or antifungal resist-  
16       ant pathogen, including novel or emerging in-  
17       fectious pathogens; or

18           “(B) qualifying pathogens listed by the  
19       Secretary under subsection (f).”.

20       (b) PRIORITY REVIEW.—Section 524A(a) of the Fed-  
21       eral Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a))  
22       is amended by inserting “of this Act, or section 351(a)  
23       of the Public Health Service Act, that requires clinical  
24       data (other than bioavailability studies) to demonstrate  
25       safety or effectiveness” before the period.

1 **SEC. 502. MODERNIZING CLINICAL TRIALS.**

2 (a) CLARIFYING THE USE OF DIGITAL HEALTH  
3 TECHNOLOGIES IN CLINICAL TRIALS.—

4 (1) IN GENERAL.—Not later than 1 year after  
5 the date of enactment of this Act, the Secretary of  
6 Health and Human Services (referred to in this sec-  
7 tion as the “Secretary”) shall issue or revise draft  
8 guidance regarding the appropriate use of validated  
9 digital health technologies in clinical trials to help  
10 improve recruitment for, retention in, participation  
11 in, and data collection during, clinical trials, and  
12 provide for novel clinical trial designs utilizing such  
13 technology for purposes of supporting the develop-  
14 ment of, and review of applications for, drugs and  
15 devices. Not later than 18 months after the public  
16 comment period on such draft guidance ends, the  
17 Secretary shall issue a revised draft guidance or  
18 final guidance.

19 (2) CONTENT.—The guidance described in  
20 paragraph (1) shall include—

21 (A) recommendations for data collection  
22 methodologies by which sponsors may incor-  
23 porate the use of digital health technologies in  
24 clinical trials to collect data remotely from trial  
25 participants;

1 (B) considerations for privacy and security  
2 protections for data collected during a clinical  
3 trial, including—

4 (i) recommendations for the protec-  
5 tion of trial participant data that is col-  
6 lected or used in research, using digital  
7 health technologies;

8 (ii) compliance with the regulations  
9 promulgated under section 264(c) of the  
10 Health Insurance Portability and Account-  
11 ability Act of 1996 (42 U.S.C. 1320d–2  
12 note), subpart B of part 50 of title 21,  
13 Code of Federal Regulations, subpart C of  
14 part 56 of title 21, Code of Federal Regu-  
15 lations, the Federal policy for the protec-  
16 tion of human subjects under subpart A of  
17 part 46 of title 45, Code of Federal Regu-  
18 lations (commonly known as the “Common  
19 Rule”), and part 2 of title 42, Code of  
20 Federal Regulations (or any successor reg-  
21 ulations); and

22 (iii) recommendations for protection  
23 of clinical trial participant data against cy-  
24 bersecurity threats, as applicable;

1 (C) considerations on data collection meth-  
2 ods to help increase recruitment of clinical trial  
3 participants and the level of participation of  
4 such participants, reduce burden on clinical  
5 trial participants, and optimize data quality;

6 (D) recommendations for the use of elec-  
7 tronic methods to obtain informed consent from  
8 clinical trial participants, taking into consider-  
9 ation applicable Federal law, including subpart  
10 B of part 50 of title 21, Code of Federal Regu-  
11 lations (or successor regulations), and, as ap-  
12 propriate, State law;

13 (E) best practices for communication and  
14 early engagement between sponsors and the  
15 Secretary on the development of data collection  
16 methods;

17 (F) the appropriate format to submit such  
18 data to the Secretary;

19 (G) a description of the manner in which  
20 the Secretary may assess or evaluate data col-  
21 lected through digital health technologies to  
22 support the development of the drug or device;

23 (H) recommendations regarding the data  
24 and information needed to demonstrate that a  
25 digital health technology is fit-for-purpose for a



1 clinical trial, and a description of how the Sec-  
2 retary will evaluate such data and information;  
3 and

4 (I) recommendations for increasing access  
5 to, and the use of, digital health technologies in  
6 clinical trials to facilitate the inclusion of di-  
7 verse and underrepresented populations, as ap-  
8 propriate, including considerations for access to,  
9 and the use of, digital health technologies in  
10 clinical trials by people with disabilities and pe-  
11 diatric populations.

12 (b) ADVANCING DECENTRALIZED CLINICAL  
13 TRIALS.—

14 (1) IN GENERAL.—Not later than 1 year after  
15 the date of enactment of this Act, the Secretary  
16 shall issue or revise draft guidance to provide rec-  
17 ommendations to clarify and advance the use of de-  
18 centralized clinical trials to support the development  
19 of drugs and devices and help improve trial partici-  
20 pant engagement and advance the use of flexible and  
21 novel clinical trial designs. Not later than 18 months  
22 after the public comment period on such draft guid-  
23 ance ends, the Secretary shall issue a revised draft  
24 guidance or final guidance.

1           (2) CONTENT.—The guidance described in  
2 paragraph (1) shall include—

3           (A) recommendations for methods of re-  
4 mote data collection, including trial participant  
5 experience data, though the use of digital health  
6 technologies, telemedicine, local laboratories,  
7 local health care providers, or other options for  
8 data collection;

9           (B) considerations for sponsors to mini-  
10 mize or reduce burdens for clinical trial partici-  
11 pants associated with participating in a clinical  
12 trial, such as the use of digital technologies,  
13 telemedicine, local laboratories, local health care  
14 providers, or other data collection or assessment  
15 options, health care provider home visits, direct-  
16 to-participant shipping of investigational drugs  
17 and devices, and electronic informed consent, as  
18 appropriate;

19           (C) recommendations regarding conducting  
20 decentralized clinical trials to facilitate and en-  
21 courage diversity among the clinical trial par-  
22 ticipants, as appropriate;

23           (D) recommendations for strategies and  
24 methods for recruiting, retaining, and engaging  
25 with clinical trial participants, including com-

1           munication regarding the role of trial partici-  
2           pants and community partners to facilitate clin-  
3           ical trial recruitment and engagement, including  
4           with respect to diverse and underrepresented  
5           populations, as appropriate;

6           (E) considerations for review and oversight  
7           by sponsors and institutional review boards, in-  
8           cluding remote trial oversight;

9           (F) recommendations for decentralized  
10          clinical trial protocol designs and processes for  
11          evaluating such proposed trial designs;

12          (G) recommendations for digital health  
13          technology and other remote assessment tools  
14          that may support decentralized clinical trials,  
15          including guidance on appropriate technological  
16          platforms and tools, data collection and use,  
17          data integrity, and communication to clinical  
18          trial participants through such technology;

19          (H) a description of the manner in which  
20          the Secretary will assess or evaluate data col-  
21          lected within a decentralized clinical trial to  
22          support the development of the drug or device,  
23          if the manner is different from that used for a  
24          non-decentralized trial;

1 (I) considerations for sponsors to validate  
2 digital technologies and establish appropriate  
3 clinical endpoints for use in decentralized trials;

4 (J) considerations for privacy and security  
5 of personally identifiable information of trial  
6 participants; and

7 (K) considerations for conducting clinical  
8 trials using centralized approaches in conjunc-  
9 tion with decentralized approaches.

10 (c) SEAMLESS AND CONCURRENT CLINICAL  
11 TRIALS.—

12 (1) IN GENERAL.—Not later than 1 year after  
13 the date of enactment of this Act, the Secretary  
14 shall issue or revise draft guidance on the use of  
15 seamless, concurrent, and other innovative clinical  
16 trial designs to support the expedited development  
17 and review of applications for drugs, as appropriate.  
18 Not later than 18 months after the public comment  
19 period on such draft guidance ends, the Secretary  
20 shall issue a revised draft guidance or final guid-  
21 ance.

22 (2) CONTENT.—The guidance described in  
23 paragraph (1) shall include—

24 (A) recommendations on the use of expan-  
25 sion cohorts and other seamless clinical trial de-

1 signs to assess different aspects of product can-  
2 didates in one continuous trial, including how  
3 such clinical trial designs can be used as part  
4 of meeting the substantial evidence standard  
5 under section 505(d) of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 355(d));

7 (B) recommendations on the use of clinical  
8 trial designs that involve the concurrent con-  
9 duct of different or multiple clinical trial  
10 phases, and the concurrent conduct of pre-  
11 clinical testing, to expedite the development of  
12 new drugs and facilitate the timely collection of  
13 data;

14 (C) recommendations for how to streamline  
15 trial logistics and facilitate the efficient collec-  
16 tion and analysis of clinical trial data, including  
17 any planned interim analyses and how such  
18 analyses could be used to streamline the prod-  
19 uct development and review processes;

20 (D) considerations to assist sponsors in en-  
21 suring the rights, safety, and welfare of clinical  
22 trial participants, maintaining compliance with  
23 good clinical practice regulations, minimizing  
24 risks to clinical trial data integrity, and ensur-  
25 ing the reliability of clinical trial results;

1 (E) recommendations for communication  
2 and early engagement between sponsors and the  
3 Food and Drug Administration on the develop-  
4 ment of seamless, concurrent, or other adaptive  
5 trial designs, including review of, and feedback  
6 on, clinical trial protocols; and

7 (F) a description of the manner in which  
8 the Secretary will assess or evaluate data col-  
9 lected through seamless, concurrent, or other  
10 adaptive trial designs to support the develop-  
11 ment of the drug.

12 (d) INTERNATIONAL HARMONIZATION.—The Sec-  
13 retary shall work with foreign regulators pursuant to  
14 memoranda of understanding or other arrangements gov-  
15 erning the exchange of information to facilitate inter-  
16 national harmonization of the regulation and use of decen-  
17 tralized clinical trials, digital technology in clinical trials,  
18 and seamless, concurrent, and other adaptive or innovative  
19 clinical trial designs.

20 **SEC. 503. ACCELERATING COUNTERMEASURE DEVELOP-**  
21 **MENT AND REVIEW.**

22 Section 565 of the Federal Food, Drug, and Cosmetic  
23 Act (21 U.S.C. 360bbb-4) is amended by adding at the  
24 end the following:

1       “(h) ACCELERATING COUNTERMEASURE DEVELOP-  
2   MENT AND REVIEW DURING AN EMERGENCY.—

3               “(1) ACCELERATION OF COUNTERMEASURE DE-  
4   VELOPMENT AND REVIEW.—The Secretary may, at  
5   the request of the sponsor of a countermeasure, dur-  
6   ing a domestic, military, or public health emergency  
7   or material threat described in section  
8   564A(a)(1)(C), expedite the development and review  
9   of countermeasures that are intended to address  
10  such domestic, military, or public health emergency  
11  or material threat for approval, licensure, clearance,  
12  or authorization under this title or section 351 of  
13  the Public Health Service Act.

14              “(2) ACTIONS.—The actions to expedite the de-  
15  velopment and review of a countermeasure under  
16  paragraph (1) may include the following:

17                   “(A) Expedited review of submissions  
18                   made by sponsors of countermeasures to the  
19                   Food and Drug Administration, including roll-  
20                   ing submissions of countermeasure applications  
21                   and other submissions.

22                   “(B) Expedited and increased engagement  
23                   with sponsors regarding countermeasure devel-  
24                   opment and manufacturing, including—

1           “(i) holding meetings with the sponsor  
2           and the review team and providing timely  
3           advice to, and interactive communication  
4           with, the sponsor regarding the develop-  
5           ment of the countermeasure to ensure that  
6           the development program to gather the  
7           nonclinical and clinical data necessary for  
8           approval, licensure, clearance, or author-  
9           ization is as efficient as practicable;

10           “(ii) involving senior managers and  
11           experienced review staff, as appropriate, in  
12           a collaborative, cross-disciplinary review;

13           “(iii) assigning a cross-disciplinary  
14           project lead for the review team to facili-  
15           tate;

16           “(iv) taking steps to ensure that the  
17           design of the clinical trials is as efficient as  
18           practicable, when scientifically appropriate,  
19           such as by minimizing the number of pa-  
20           tients exposed to a potentially less effica-  
21           cious treatment; and

22           “(v) streamlining the review of ap-  
23           proved, licensed, cleared, or authorized  
24           countermeasures to treat or prevent new or



1 emerging threats, including the review of  
2 any changes to such countermeasures.

3 “(C) Expedited issuance of guidance docu-  
4 ments and publication of other regulatory infor-  
5 mation regarding countermeasure development  
6 and manufacturing.

7 “(D) Other steps to expedite the develop-  
8 ment and review of a countermeasure applica-  
9 tion submitted for approval, licensure, clear-  
10 ance, or authorization, as the Secretary deter-  
11 mines appropriate.

12 “(3) LIMITATION OF EFFECT.—Nothing in this  
13 subsection shall be construed to require the Sec-  
14 retary to grant, or take any other action related to,  
15 a request of a sponsor to expedite the development  
16 and review of a countermeasure for approval, licen-  
17 sure, clearance, or authorization under paragraph  
18 (1).”.

19 **SEC. 504. THIRD PARTY TEST EVALUATION DURING EMER-**  
20 **GENCIES.**

21 (a) IN GENERAL.—Section 565 of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as amend-  
23 ed by section 503, is further amended by adding at the  
24 end the following:

1       “(i) THIRD PARTY EVALUATION OF TESTS USED  
2 DURING AN EMERGENCY.—

3           “(1) IN GENERAL.—For purposes of conducting  
4 evaluations regarding whether an in vitro diagnostic  
5 product (as defined in section 809.3 of title 21, Code  
6 of Federal Regulations (or any successor regula-  
7 tions)) for which a request for emergency use au-  
8 thorization is submitted under section 564 meets the  
9 criteria for issuance of such authorization, the Sec-  
10 retary may, as appropriate, consult with persons  
11 with appropriate expertise with respect to such eval-  
12 uations or enter into cooperative agreements or con-  
13 tracts with such persons under which such persons  
14 conduct such evaluations and make such rec-  
15 ommendations, including, as appropriate, evaluations  
16 and recommendations regarding the scope of author-  
17 ization and conditions of authorization.

18           “(2) REQUIREMENTS REGARDING EVALUATIONS  
19 AND RECOMMENDATIONS.—

20           “(A) IN GENERAL.—In evaluating and  
21 making recommendations to the Secretary re-  
22 garding the validity, accuracy, and reliability of  
23 in vitro diagnostic products, as described in  
24 paragraph (1), a person shall consider and doc-  
25 ument whether the relevant criteria under sub-

1 section (c)(2) of section 564 for issuance of au-  
2 thorization under such section are met with re-  
3 spect to the in vitro diagnostic product.

4 “(B) WRITTEN RECOMMENDATIONS.—Rec-  
5 ommendations made by a person under this  
6 subsection shall be submitted to the Secretary  
7 in writing, and shall include the reasons for  
8 such recommendation and other information  
9 that may be requested by the Secretary.

10 “(3) RULE OF CONSTRUCTION.— Nothing in  
11 this subsection shall be construed to require the Sec-  
12 retary to consult with, or enter into cooperative  
13 agreements or contracts with, persons as described  
14 in paragraph (1) for purposes of authorizing an in  
15 vitro diagnostic product or otherwise affecting the  
16 emergency use authorization authorities under this  
17 section or section 564.”.

18 (b) GUIDANCE.—Not later than 1 year after the date  
19 of enactment of this Act, the Secretary of Health and  
20 Human Services (referred to in this subsection as the  
21 “Secretary”) shall issue draft guidance on consultations  
22 with persons under subsection (i) of section 565 of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 360bbb-4), as added by subsection (a), including consider-  
25 ations concerning conflicts of interest, compensation ar-

1 rangements, and information sharing. Not later than 1  
2 year after the public comment period on such draft guid-  
3 ance ends, the Secretary shall issue a revised draft guid-  
4 ance or final guidance.

5 **SEC. 505. FACILITATING THE USE OF REAL WORLD EVI-**  
6 **DENCE.**

7 Not later than 1 year after the date of enactment  
8 of this Act, the Secretary of Health and Human Services  
9 shall issue or revise existing guidance on considerations  
10 for the use of real world data and real world evidence to  
11 support regulatory decision-making, as follows:

12 (1) With respect to drugs, such guidance shall  
13 address the use of such data and evidence to support  
14 the approval of a drug application under section 505  
15 of the Federal Food, Drug, and Cosmetic Act (21  
16 U.S.C. 355) or a biological product application  
17 under section 351 of the Public Health Service Act  
18 (42 U.S.C. 262), or to support an investigational use  
19 exemption under section 505(i) of the Federal Food,  
20 Drug, and Cosmetic Act or section 351(a)(3) of the  
21 Public Health Service Act. Such guidance shall in-  
22 clude considerations for the inclusion, in such appli-  
23 cations, of real world data and real world evidence  
24 obtained as a result of the use of drugs authorized  
25 for emergency use under section 564 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–  
2 3), and considerations for standards and methodolo-  
3 gies for collection and analysis of real world evidence  
4 included in such applications, submissions, or re-  
5 quests, as appropriate.

6 (2) With respect to devices, such guidance shall  
7 address the use of such data and evidence to support  
8 the approval, clearance, or classification of a device  
9 pursuant to an application or submission submitted  
10 under section 510(k), 513(f)(2), or 515 of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
12 360(k), 360e(f)(2), 360e), or to support an inves-  
13 tigational use exemption under section 520(g) of  
14 such Act (21 U.S.C. 360j(g)). Such guidance shall  
15 include considerations for the inclusion, in such ap-  
16 plications, submissions, or requests, of real world  
17 data and real world evidence obtained as a result of  
18 the use of devices authorized for emergency use  
19 under section 564 of the Federal Food, Drug, and  
20 Cosmetic Act (21 U.S.C. 360bbb–3), and consider-  
21 ations for standards and methodologies for collection  
22 and analysis of real world evidence included in such  
23 applications, submissions, or requests, as appro-  
24 priate.

1 **SEC. 506. PLATFORM TECHNOLOGIES.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,  
3 Drug, and Cosmetic Act is amended by inserting after sec-  
4 tion 506J of such Act (21 U.S.C. 356j) the following:

5 **“SEC. 506K. PLATFORM TECHNOLOGIES.**

6 “(a) IN GENERAL.—The Secretary shall establish a  
7 process for the designation of platform technologies that  
8 meet the criteria described in subsection (b).

9 “(b) CRITERIA.—A platform technology incorporated  
10 within or utilized by a drug is eligible for designation as  
11 a designated platform technology under this section if—

12 “(1) the platform technology is incorporated in,  
13 or utilized by, a drug approved under section 505 of  
14 this Act or a biological product licensed under sec-  
15 tion 351 of the Public Health Service Act;

16 “(2) preliminary evidence submitted by the  
17 sponsor of the approved or licensed drug described  
18 in paragraph (1), or a sponsor that has been grant-  
19 ed a right of reference to data submitted in the ap-  
20 plication for such drug, demonstrates that the plat-  
21 form technology has the potential to be incorporated  
22 in, or utilized by, more than one drug without an ad-  
23 verse effect on quality, manufacturing, or safety;  
24 and

25 “(3) data or information submitted by the ap-  
26 plicable person under paragraph (2) indicates that

1 incorporation or utilization of the platform tech-  
2 nology has a reasonable likelihood to bring signifi-  
3 cant efficiencies to the drug development or manu-  
4 facturing process and to the review processes.

5 “(c) REQUEST FOR DESIGNATION.—A person may  
6 request the Secretary designate a platform technology as  
7 a designated platform technology concurrently with, or at  
8 any time after, submission under section 505(i) of this Act  
9 or section 351(a)(3) of the Public Health Service Act for  
10 the investigation of a drug that incorporates or utilizes  
11 the platform technology that is the subject of the request.

12 “(d) DESIGNATION.—

13 “(1) IN GENERAL.—Not later than 60 calendar  
14 days after the receipt of a request under subsection  
15 (c), the Secretary shall determine whether the plat-  
16 form technology that is the subject of the request  
17 meets the criteria described in subsection (b).

18 “(2) DESIGNATION.—If the Secretary deter-  
19 mines that the platform technology meets the cri-  
20 teria described in subsection (b), the Secretary shall  
21 designate the platform technology as a designated  
22 platform technology and may expedite the develop-  
23 ment and review of any subsequent application sub-  
24 mitted under section 505(b) of this Act or section  
25 351(a) of the Public Health Service Act for a drug

1 that uses or incorporates the platform technology  
2 pursuant to subsection (e), as appropriate.

3 “(3) DETERMINATION NOT TO DESIGNATE.—If  
4 the Secretary determines that the platform tech-  
5 nology does not meet the criteria under subsection  
6 (b), the Secretary shall include with the determina-  
7 tion not to designate the technology a written de-  
8 scription of the rationale for such determination.

9 “(4) REVOCATION OF DESIGNATION.—The Sec-  
10 retary may revoke a designation made under para-  
11 graph (2), if the Secretary determines that the des-  
12 ignated platform technology no longer meets the cri-  
13 teria described in subsection (b). The Secretary shall  
14 communicate the determination to revoke a designa-  
15 tion to the requesting sponsor in writing, including  
16 a description of the rationale for such determination.

17 “(5) APPLICABILITY.—Nothing in this section  
18 shall prevent a product that uses or incorporates a  
19 designated platform technology from being eligible  
20 for expedited approval pathways if it is otherwise eli-  
21 gible under this Act or the Public Health Service  
22 Act.

23 “(e) ACTIONS.—The Secretary may take actions to  
24 expedite the development and review of an application for



1 a drug that incorporates or utilizes a designated platform  
2 technology, including—

3 “(1) engaging in early interactions with the  
4 sponsor to discuss the use of the designated plat-  
5 form technology and what is known about such tech-  
6 nology, including data previously submitted that is  
7 relevant to establishing, as applicable, safety or effi-  
8 cacy under section 505(b) of this Act or safety, pu-  
9 rity, or potency under section 351(a) of the Public  
10 Health Service Act;

11 “(2) providing timely advice to, and interactive  
12 communication with, the sponsor regarding the de-  
13 velopment of the drug that proposes to use the des-  
14 ignated platform technology to ensure that the devel-  
15 opment program designed to gather data necessary  
16 for approval or licensure is as efficient as prac-  
17 ticable, which may include holding meetings with the  
18 sponsor and the review team throughout the develop-  
19 ment of the drug; and

20 “(3) considering inspectional findings, including  
21 prior findings, related to the manufacture of a drug  
22 that incorporates or utilizes the designated platform  
23 technology.

24 “(f) LEVERAGING DATA FROM DESIGNATED PLAT-  
25 FORM TECHNOLOGIES.—The Secretary shall, consistent

1 with applicable standards for approval, authorization, or  
2 licensure under this Act and section 351(a) of the Public  
3 Health Service Act, allow the sponsor of an application  
4 under section 505(b) of this Act or section 351(a) of the  
5 Public Health Service Act or a request for emergency use  
6 authorization under section 564, in order to support ap-  
7 proval, licensure, or authorization, to reference or rely  
8 upon data and information within such application or re-  
9 quest that incorporates or utilizes the same or substan-  
10 tially similar platform technology designated under sub-  
11 section (d), provided that—

12           “(1) such data and information was submitted  
13           by the same sponsor, pursuant to the application for  
14           the drug with respect to which designation of the  
15           designated platform technology under subsection (d)  
16           was granted; or

17           “(2) the sponsor relying on such data and in-  
18           formation received a right of reference to such data  
19           and information from the sponsor described in para-  
20           graph (1).

21           “(g) CHANGES TO A DESIGNATED PLATFORM TECH-  
22           NOLOGY.—A sponsor of one or more applications approved  
23           under section 505(b) of this Act or section 351(a) of the  
24           Public Health Service Act for a drug or biological product  
25           that incorporates or utilizes the same designated platform

1 technology may submit a single supplemental application  
2 for the same proposed changes to the designated platform  
3 technology that is applicable to more than one drug or  
4 biological product that incorporates or utilizes such des-  
5 ignated platform technology that may be cross referenced  
6 in other applications incorporating such change. Such ap-  
7 plication may include one or more comparability protocols  
8 regarding how such changes to the platform technology  
9 would be made for each applicable application.

10       “(h) GUIDANCE.—Not later than 1 year after the  
11 date of enactment of this section, the Secretary shall issue  
12 draft guidance on the implementation of this section. Such  
13 guidance shall include examples of drugs that can be man-  
14 ufactured using platform technologies, including drugs  
15 that contain or consist of vectors and nucleic acids, infor-  
16 mation about the Secretary’s review of platform tech-  
17 nologies, information regarding submitting for designa-  
18 tion, consideration for persons submitting a request for  
19 designation who has been granted a right of reference, the  
20 implementation of the designated platform technology des-  
21 ignation program, efficiencies that may be achieved in the  
22 development and review of products that incorporate or  
23 utilize designated platform technologies, and recommenda-  
24 tions and requirements for making and reporting manu-

1 facturing changes to a designated platform technology in  
2 accordance with section 506A.

3 “(i) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘platform technology’ means—

5 “(A) a technology incorporated into a drug  
6 or biological product, such as a nucleic acid se-  
7 quence, molecular structure, mechanism of ac-  
8 tion, delivery method, or other technology the  
9 Secretary determines to be appropriate, or com-  
10 bination of any such technologies, that—

11 “(i) is essential to the characterization  
12 of the drug or biological product; and

13 “(ii) can be adapted for, or incor-  
14 porated or utilized in, more than one drug  
15 or biological product sharing common  
16 structural elements; or

17 “(B) a standardized production or manu-  
18 facturing process that is used to create or de-  
19 velop more than one drug sharing common  
20 structural elements that can be incorporated  
21 into multiple different drugs.

22 “(2) The term ‘designated platform technology’  
23 means a platform technology that is designated as a  
24 platform technology under subsection (d).

1       “(j) RULE OF CONSTRUCTION.—Nothing in this sec-  
2 tion shall be construed to—

3               “(1) alter the authority of the Secretary to ap-  
4 prove drugs pursuant to section 505 of this Act or  
5 license biological products pursuant to section 351 of  
6 the Public Health Service Act, including standards  
7 of evidence and applicable conditions for approval or  
8 licensure under the applicable Act; or

9               “(2) confer any new rights with respect to the  
10 permissibility of a sponsor of an application for a  
11 drug product or biological product referencing infor-  
12 mation contained in another application submitted  
13 by the holder of an approved application under sec-  
14 tion 505(c) of this Act or of a license under section  
15 351(a) of the Public Health Service Act.”.

16       (b) REPORT.—Not later than 2 years after the date  
17 of enactment of this Act, the Secretary of Health and  
18 Human Services shall issue a report to the Committee on  
19 Health, Education, Labor, and Pensions of the Senate and  
20 the Committee on Energy and Commerce of the House  
21 of Representatives, on the platform technology designation  
22 program under section 506K of the Federal Food, Drug,  
23 and Cosmetic Act, as added by subsection (a). Such report  
24 shall include—

1           (1) the number of requests for designation  
2 under such program;

3           (2) the number of designations under such pro-  
4 gram issued, active, and revoked;

5           (3) the resources required to carry out such  
6 program (including the review time used for full-  
7 time equivalent employees);

8           (4) any efficiencies gained in the development,  
9 manufacturing, and review processes associated with  
10 such designations; and

11           (5) recommendations, if any, to strengthen the  
12 program to better leverage platform technologies  
13 that can be used in more than one drug and meet  
14 patient needs in a manner as timely as possible, tak-  
15 ing into consideration the resources available to the  
16 Secretary of Health and Human Services for car-  
17 rying out such program.

18 **SEC. 507. INCREASING EUA DECISION TRANSPARENCY.**

19           Section 564(h)(1) of the Federal Food, Drug, and  
20 Cosmetic Act (21 U.S.C. 360bbb-3(h)(1)) is amended—

21           (1) by inserting “on the internet website of the  
22 Food and Drug Administration and” after “prompt-  
23 ly publish”; and

24           (2) by striking “application under section  
25 505(i), 512(j), or 520(g), even if such summary may

1 indirectly reveal the existence of such application”  
2 and inserting “application, request, or submission  
3 under this section or section 505(b), 505(i), 505(j),  
4 512(b), 512(j), 512(n), 515, 510(k), 513(f)(2),  
5 520(g), 520(m), 571, or 572 of this Act, or section  
6 351(a) or 351(k) of the Public Health Service Act,  
7 even if such summary may reveal the existence of  
8 such an application, request, or submission, or data  
9 contained in such application, request, or submis-  
10 sion”.

11 **SEC. 508. IMPROVING FDA GUIDANCE AND COMMUNICA-**  
12 **TION.**

13 (a) FDA REPORT AND IMPLEMENTATION OF GOOD  
14 GUIDANCE PRACTICES.—The Secretary of Health and  
15 Human Services (referred to in this section as the “Sec-  
16 retary”) shall develop, and publish on the website of the  
17 Food and Drug Administration—

18 (1) a report identifying best practices for the  
19 efficient prioritization, development, issuance, and  
20 use of guidance documents, within centers, across  
21 the Food and Drug Administration, and across other  
22 applicable agencies; and

23 (2) a plan for implementation of such best  
24 practices, including across other applicable agencies,  
25 which shall address—

1 (A) streamlining development and review  
2 of guidance documents within centers and  
3 across the Food and Drug Administration;

4 (B) streamlining processes for regulatory  
5 submissions to the Food and Drug Administra-  
6 tion, including through the revision or issuance  
7 of guidance documents; and

8 (C) implementing innovative guidance de-  
9 velopment processes and practices and  
10 transitioning or updating guidance issued dur-  
11 ing the COVID–19 public health emergency, as  
12 appropriate.

13 (b) REPORT AND IMPLEMENTATION OF FDA BEST  
14 PRACTICES FOR COMMUNICATING WITH EXTERNAL  
15 STAKEHOLDERS.—The Secretary, acting through the  
16 Commissioner of Food and Drugs, shall develop and pub-  
17 lish on the website of the Food and Drug Administration  
18 a report on the practices of the Food and Drug Adminis-  
19 tration to broadly communicate with external stake-  
20 holders, other than through guidance documents, which  
21 shall include—

22 (1) a review of the types and methods of public  
23 communication that the Food and Drug Administra-  
24 tion uses to communicate and interact with medical  
25 product sponsors and other external stakeholders;



1           (2) the identification of best practices for the  
2 efficient development, issuance, and use of such  
3 communications; and

4           (3) a plan for implementation of best practices  
5 for communication with external stakeholders, which  
6 shall address—

7           (A) advancing the use of innovative forms  
8 of communication, including novel document  
9 types and formats, to provide increased regu-  
10 latory clarity to product sponsors and other  
11 stakeholders, and advancing methods of com-  
12 municating and interacting with medical prod-  
13 uct sponsors and other external stakeholders,  
14 including the use of tools such as product sub-  
15 mission templates, webinars, and frequently  
16 asked questions communications;

17           (B) streamlining processes for regulatory  
18 submissions; and

19           (C) implementing innovative communica-  
20 tion development processes and transitioning or  
21 updating communication practices used during  
22 the COVID–19 public health emergency, as ap-  
23 propriate.

24           (c) CONSULTATION.—In developing and publishing  
25 the report and implementation plan under this section, the

1 Secretary shall consult with stakeholders, including re-  
2 searchers, academic organizations, pharmaceutical, bio-  
3 technology, and medical device developers, clinical re-  
4 search organizations, clinical laboratories, health care pro-  
5 viders, patient groups, and other appropriate stakeholders.

6 (d) MANNER OF ISSUANCE.—For purposes of car-  
7 rying out this section, the Secretary may update an exist-  
8 ing report or plan, and may combine the reports and im-  
9 plementation plans described in subsections (a) and (b)  
10 into one or more documents.

11 (e) TIMING.—The Secretary shall—

12 (1) not later than 1 year after the date of en-  
13 actment of this Act, publish a draft of the reports  
14 and plans required under this section; and

15 (2) not later than 180 days after publication of  
16 the draft reports and plans under paragraph (1)—

17 (A) publish a final report and plan; and

18 (B) begin implementation of the best prac-  
19 tices pursuant to such final plan.

20 **SEC. 509. GAO STUDY AND REPORT ON HIRING CHAL-**  
21 **LENGES AT FDA.**

22 (a) IN GENERAL.—Not later than 18 months after  
23 the date of enactment of this Act, the Comptroller General  
24 of the United States shall submit to the Committee on  
25 Health, Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the House  
2 of Representatives a report assessing the policies, prac-  
3 tices, processes, and programs of the Food and Drug Ad-  
4 ministration with respect to hiring, recruiting, and reten-  
5 tion, and the impact of such policies, practices, processes,  
6 and programs on the agency's ability to carry out its pub-  
7 lic health mission, including the agency's ability to respond  
8 to the COVID-19 public health emergency. Such report  
9 may involve policies, practices, processes, and programs  
10 of the Department of Health and Human Services and  
11 other agencies, as applicable.

12 (b) CONTENT OF REPORT.—The report required  
13 under subsection (a) shall include an assessment of—

14 (1) challenges related to the efficient hiring, re-  
15 cruiting, professional development, and retention of  
16 the Food and Drug Administration workforce, in-  
17 cluding, as applicable, the end-to-end hiring process,  
18 time to hire, multiple hiring authorities, salary lev-  
19 els, vacancy rates, and identification and availability  
20 of candidates with necessary expertise;

21 (2) causes of the challenges identified under  
22 paragraph (1), including an analysis of relevant poli-  
23 cies, practices, processes, programs, organizational  
24 structure, resources, training, remote work capabili-  
25 ties, and data systems;

1           (3) challenges facing the Food and Drug Ad-  
2           ministration workforce, including with respect to  
3           workload, diversity, employee engagement, and mo-  
4           rale;

5           (4) the impact of challenges identified under  
6           paragraphs (1) and (3) on operations of the Food  
7           and Drug Administration, including on meeting user  
8           fee agreement performance goals and inspection ac-  
9           tivities;

10          (5) any hiring or retention plans of the Food  
11          and Drug Administration, and progress towards im-  
12          plementation and the metrics to measure success of  
13          such plans;

14          (6) successful or efficient hiring policies or au-  
15          thorities, including any relevant hiring authorities  
16          that resulted in efficient hiring for vacant positions,  
17          such as temporary direct hiring authorities during  
18          the COVID–19 public health emergency response;

19          (7) whether policies, practices, processes, and  
20          programs related to hiring, recruiting, professional  
21          development, and retention are implemented consist-  
22          ently across the Food and Drug Administration;

23          (8) recommendations to address challenges  
24          identified, including recommendations regarding im-  
25          provements to policies, practices, processes, and pro-

1 grams of the Food and Drug Administration with  
2 respect to hiring, recruiting, professional develop-  
3 ment, and retention; and

4 (9) challenges related to hiring, recruiting, and  
5 retaining a qualified workforce to meet public health  
6 emergency response needs, including any such chal-  
7 lenges identified during the COVID–19 public health  
8 emergency.

## 9 **Subtitle B—Mitigating Shortages**

### 10 **SEC. 511. ENSURING REGISTRATION OF FOREIGN DRUG** 11 **AND DEVICE MANUFACTURERS.**

12 (a) REGISTRATION OF CERTAIN FOREIGN ESTAB-  
13 LISHMENTS.—Section 510(i) of the Federal Food, Drug,  
14 and Cosmetic Act (21 U.S.C. 360(i)) is amended by add-  
15 ing at the end the following:

16 “(5) The requirements of paragraphs (1) and (2)  
17 shall apply regardless of whether the drug or device under-  
18 goes further manufacture, preparation, propagation,  
19 compounding, or processing at a separate establishment  
20 outside the United States prior to being imported or of-  
21 fered for import into the United States.”.

22 (b) UPDATING REGULATIONS.—Not later than 2  
23 years after the date of enactment of this Act, the Sec-  
24 retary of Health and Human Services shall update regula-

1 tions, as appropriate, to implement the amendment made  
2 by subsection (a).

3 **SEC. 512. EXTENDING EXPIRATION DATES FOR CERTAIN**  
4 **DRUGS.**

5 (a) IN GENERAL.—Not later than 1 year after the  
6 date of enactment of this Act, the Secretary of Health and  
7 Human Services (referred to in this section as the “Sec-  
8 retary”) shall issue draft guidance, or revise existing guid-  
9 ance, to address recommendations for sponsors of applica-  
10 tions submitted under section 505 of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 355) or section 351  
12 of the Public Health Service Act (42 U.S.C. 262) regard-  
13 ing—

14 (1) the submission of stability testing data in  
15 such applications, including considerations for data  
16 requirements that could be streamlined or reduced  
17 to facilitate faster review of longer proposed expira-  
18 tion dates;

19 (2) establishing in the labeling of drugs the  
20 longest feasible expiration date scientifically sup-  
21 ported by such data, taking into consideration how  
22 extended expiration dates may—

23 (A) help prevent or mitigate drug short-  
24 ages; and

25 (B) affect product quality; and

1           (3) the use of innovative approaches for drug  
2           and combination product stability modeling to sup-  
3           port initial product expiration dates and expiration  
4           date extensions.

5           (b) REPORT.—Not later than 2 years after the date  
6           of enactment of this Act, and again 2 years thereafter,  
7           the Secretary shall submit to the Committee on Health,  
8           Education, Labor, and Pensions of the Senate and the  
9           Committee on Energy and Commerce of the House of  
10          Representatives a report that includes—

11           (1) the number of drugs for which the Sec-  
12          retary has requested the manufacturer make a label-  
13          ing change regarding the expiration date; and

14           (2) for each drug for which the Secretary has  
15          requested a labeling change with respect to the expi-  
16          ration date, information regarding the circumstances  
17          of such request, including—

18           (A) the name and dose of such drug;

19           (B) the rationale for the request;

20           (C) whether the drug, at the time of the  
21          request, was listed on the drug shortage list  
22          under section 506E of the Federal Food, Drug,  
23          and Cosmetic Act (21 U.S.C. 356e), or was at  
24          risk of shortage;

1 (D) whether the request was made during  
2 a public health emergency declared under sec-  
3 tion 319 of the Public Health Service Act (42  
4 U.S.C. 247d); and

5 (E) whether the manufacturer made the  
6 requested change by the requested date, and for  
7 instances where the manufacturer does not  
8 make the requested change, the manufacturer's  
9 justification for not making the change, if the  
10 manufacturer agrees to provide such justifica-  
11 tion for inclusion in the report.

12 **SEC. 513. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**  
13 **PILOT PROGRAM.**

14 (a) IN GENERAL.—The Secretary of Health and  
15 Human Services (referred to in this section as the “Sec-  
16 retary”) shall conduct a pilot program under which the  
17 Secretary increases the conduct of unannounced inspec-  
18 tions of foreign human drug facilities and evaluates the  
19 differences between inspections of domestic and foreign  
20 human drug facilities, including the impact of announcing  
21 inspections to persons who own or operate foreign human  
22 drug facilities in advance of an inspection. Such pilot pro-  
23 gram shall evaluate—

24 (1) differences in the number and type of viola-  
25 tions of section 501(a)(2)(B) of the Federal Food,



1 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))  
2 identified during unannounced and announced in-  
3 spections of foreign human drug facilities and any  
4 other significant differences between each type of in-  
5 spection;

6 (2) costs and benefits associated with con-  
7 ducting announced and unannounced inspections of  
8 foreign human drug facilities;

9 (3) barriers to conducting unannounced inspec-  
10 tions of foreign human drug facilities and any chal-  
11 lenges to achieving parity between domestic and for-  
12 eign human drug facility inspections; and

13 (4) approaches for mitigating any negative ef-  
14 fects of conducting announced inspections of foreign  
15 human drug facilities.

16 (b) PILOT PROGRAM INITIATION.—The Secretary  
17 shall initiate the pilot program under this section not later  
18 than 180 days after the date of enactment of this Act.

19 (c) REPORT.—The Secretary shall, not later than 180  
20 days following the completion of the pilot program, make  
21 available on the website of the Food and Drug Administra-  
22 tion a final report on the pilot program under this section,  
23 including—

24 (1) findings and any associated recommenda-  
25 tions with respect to the evaluation under subsection

1 (a), including any recommendations to address iden-  
2 tified barriers to conducting unannounced inspec-  
3 tions of foreign human drug facilities;

4 (2) findings and any associated recommenda-  
5 tions regarding how the Secretary may achieve par-  
6 ity between domestic and foreign human drug in-  
7 spections; and

8 (3) the number of unannounced inspections  
9 during the pilot that would not be unannounced  
10 under existing practices.

11 **SEC. 514. COMBATING COUNTERFEIT DEVICES.**

12 (a) PROHIBITED ACTS.—Section 301 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
14 ed by adding at the end the following:

15 “(fff)(1) Forging, counterfeiting, simulating, or false-  
16 ly representing, or without proper authority using any  
17 mark, stamp, tag, label, or other identification upon any  
18 device or container, packaging, or labeling thereof so as  
19 to render such device a counterfeit device.

20 “(2) Making, selling, disposing of, or keeping in pos-  
21 session, control, or custody, or concealing any punch, die,  
22 plate, stone, or other thing designed to print, imprint, or  
23 reproduce the trademark, trade name, or other identifying  
24 mark or imprint of another or any likeness of any of the  
25 foregoing upon any device or container, packaging, or la-

1 being thereof so as to render such device a counterfeit  
2 device.

3 “(3) The doing of any act which causes a device to  
4 be a counterfeit device, or the sale or dispensing, or the  
5 holding for sale or dispensing, of a counterfeit device.”.

6 (b) PENALTIES.—Section 303 of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

8 (1) in subsection (b)(8), by inserting “, or who  
9 violates section 301(fff)(3) by knowingly making,  
10 selling or dispensing, or holding for sale or dis-  
11 pensing, a counterfeit device,” after “a counterfeit  
12 drug”; and

13 (2) in subsection (c), by inserting “; or (6) for  
14 having violated section 301(fff)(2) if such person  
15 acted in good faith and had no reason to believe that  
16 use of the punch, die, plate, stone, or other thing in-  
17 volved would result in a device being a counterfeit  
18 device, or for having violated section 301(fff)(3) if  
19 the person doing the act or causing it to be done  
20 acted in good faith and had no reason to believe that  
21 the device was a counterfeit device” before the pe-  
22 riod.

23 (c) SEIZURE.—Section 304(a)(2) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is  
25 amended—

1           (1) by striking “, and (E)” and inserting “,  
2           (E)”;

3           (2) by inserting “, (F) Any device that is a  
4           counterfeit device, (G) Any container, packaging, or  
5           labeling of a counterfeit device, and (H) Any punch,  
6           die, plate, stone, labeling, container, or other thing  
7           used or designed for use in making a counterfeit de-  
8           vice or devices” before the period.

9   **SEC. 515. STRENGTHENING MEDICAL DEVICE SUPPLY**  
10                                   **CHAINS.**

11           (a) IN GENERAL.—Section 506J of the Federal  
12 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is amend-  
13 ed—

14           (1) by redesignating subsections (h) and (i) as  
15           subsections (j) and (k), respectively; and

16           (2) by inserting after subsection (g) the fol-  
17           lowing:

18           “(h) RISK MANAGEMENT PLANS.—Each manufac-  
19 turer of a device that is critical to public health, including  
20 devices that are life-supporting, life-sustaining, or in-  
21 tended for use in emergency medical care, shall develop,  
22 maintain, and, as appropriate, implement a redundancy  
23 risk management plan that identifies and evaluates risks  
24 to the supply of the device, as applicable, for each estab-

1 lishment in which such device is manufactured. A risk  
2 management plan under this subsection—

3 “(1) may identify and evaluate risks to the sup-  
4 ply of more than one device, or device category,  
5 manufactured at the same establishment; and

6 “(2) shall be subject to inspection and copying  
7 by the Secretary pursuant to section 704 or at the  
8 request of the Secretary.”.

9 (b) REPORT.—Not later than 2 years after the date  
10 of enactment of this Act, and annually for 4 years there-  
11 after, the Secretary of Health and Human Services shall  
12 prepare and submit to the Committee on Health, Edu-  
13 cation, Labor, and Pensions of the Senate and the Com-  
14 mittee on Energy and Commerce of the House of Rep-  
15 resentatives a report on the use of information manufac-  
16 turers submit pursuant to section 506J of the Federal  
17 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) and ap-  
18 plicable guidance issued with respect to such section.

19 **SEC. 516. PREVENTING MEDICAL DEVICE SHORTAGES.**

20 (a) NOTIFICATIONS.—Section 506J of the Federal  
21 Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as  
22 amended by section 515, is further amended—

23 (1) in the flush text at the end of subsection  
24 (a), by inserting “or of any other circumstance that  
25 is likely to lead to a meaningful disruption in the

1 supply of the device or a shortage of the device, and  
2 there is no other available device that could reason-  
3 ably be substituted for that device in the United  
4 States” before the period;

5 (2) in subsection (f), by inserting “or (i)” after  
6 “subsection (a)”; and

7 (3) by inserting after subsection (h), as added  
8 by section 515, the following:

9 “(i) **ADDITIONAL NOTIFICATIONS.**—The Secretary  
10 may receive notifications from a manufacturers of a device  
11 that is life-supporting, life-sustaining, or intended for use  
12 in emergency medical care or during surgery, or any other  
13 device the Secretary determines to be critical to the public  
14 health, pertaining to a permanent discontinuance in the  
15 manufacture of the device (except for any discontinuance  
16 as a result of an approved modification of the device) or  
17 an interruption of the manufacture of the device that is  
18 likely to lead to a meaningful disruption in the supply of  
19 that device in the United States, and the reasons for such  
20 discontinuance or interruption.”.

21 (b) **GUIDANCE ON VOLUNTARY NOTIFICATIONS OF**  
22 **DISCONTINUANCE OR INTERRUPTION OF DEVICE MANU-**  
23 **FACTURE.**—Not later than 1 year after the date of enact-  
24 ment of this Act, the Secretary shall issue draft guidance  
25 to facilitate voluntary notifications under subsection (i) of

1 section 506J of the Federal Food, Drug, and Cosmetic  
2 Act (21 U.S.C. 356j), as added by subsection (a). Such  
3 guidance shall include a description of circumstances in  
4 which a voluntary notification under such subsection (i)  
5 may be appropriate, recommended timeframes within  
6 which sponsors should submit such a notification, the  
7 process for receiving such notifications, and actions the  
8 Secretary may take to mitigate or prevent a shortage re-  
9 sulting from a discontinuance or interruption in the manu-  
10 facture of a device for which such notification is received.  
11 The Secretary shall issue final guidance not later than 1  
12 year after the close of the comment period for the draft  
13 guidance.

14 **SEC. 517. REMOTE RECORDS ASSESSMENTS FOR MEDICAL**  
15 **DEVICES.**

16 (a) **FACTORY INSPECTION.**—Section 704(a)(4)(A) of  
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 374(a)(4)(A)) is amended—

19 (1) in the first sentence, by inserting “or de-  
20 vice” after “processing of a drug”; and

21 (2) in the second sentence, by striking “shall  
22 include” and all that follows through the period at  
23 the end and inserting the following: “shall include—

24 “(A) a description of the records re-  
25 quested; and

1           “(B) a rationale for requesting such infor-  
2           mation in advance of, or in lieu of, an inspec-  
3           tion.”.

4           (b) GUIDANCE.—Not later than 1 year after the date  
5 of enactment of this Act, the Secretary shall issue draft  
6 guidance describing circumstances in which the Secretary  
7 intends to issue requests for records or other information  
8 in advance of, or in lieu of, an inspection, processes for  
9 responding to such requests electronically or in physical  
10 form, and factors the Secretary intends to consider in eval-  
11 uating whether such records are provided within a reason-  
12 able timeframe, within reasonable limits, and in a reason-  
13 able manner, accounting for resource and other limitations  
14 that may exist, including for small businesses. The Sec-  
15 retary shall issue final guidance not later than 1 year after  
16 the close of the comment period for the draft guidance.

17 **SEC. 518. ADVANCED MANUFACTURING TECHNOLOGIES**  
18 **DESIGNATION PILOT PROGRAM.**

19           Subchapter A of chapter V of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as  
21 amended by section 506, is further amended by inserting  
22 after section 506K the following:



1 **“SEC. 506L. ADVANCED MANUFACTURING TECHNOLOGIES**  
2 **DESIGNATION PILOT PROGRAM.**

3 “(a) IN GENERAL.—Not later than 1 year after the  
4 date of enactment of this section, the Secretary shall ini-  
5 tiate a pilot program under which persons may request  
6 designation of an advanced manufacturing technology as  
7 described in subsection (b).

8 “(b) DESIGNATION PROCESS.—The Secretary shall  
9 establish a process for the designation under this section  
10 of methods of manufacturing drugs, including biological  
11 products, and active pharmaceutical ingredients of such  
12 drugs, as advanced manufacturing technologies. A method  
13 of manufacturing, or a combination of manufacturing  
14 methods, is eligible for designation as an advanced manu-  
15 facturing technology if such method or combination of  
16 methods incorporates a novel technology, or uses an estab-  
17 lished technique or technology in a novel way, that will  
18 substantially—

19 “(1) enhance drug quality; or

20 “(2) improve the manufacturing process for a  
21 drug and maintain drug quality, including by—

22 “(A) reducing development time for a drug  
23 using the designated manufacturing method; or

24 “(B) increasing or maintaining the supply  
25 of—

1                   “(i) a drug that is life-supporting,  
2                   life-sustaining, or of critical importance to  
3                   providing health care; or

4                   “(ii) a drug that is on the drug short-  
5                   age list under section 506E.

6           “(c) EVALUATION AND DESIGNATION OF AN AD-  
7           VANCED MANUFACTURING TECHNOLOGY.—

8                   “(1) SUBMISSION.—A person who requests des-  
9                   ignation of a method of manufacturing as an ad-  
10                  vanced manufacturing technology under this section  
11                  shall submit to the Secretary data or information  
12                  demonstrating that the method of manufacturing  
13                  meets the criteria described in subsection (b) in a  
14                  particular context of use. The Secretary may facili-  
15                  tate the development and review of such data or in-  
16                  formation by—

17                   “(A) providing timely advice to, and inter-  
18                   active communication with, such person regard-  
19                   ing the development of the method of manufac-  
20                   turing; and

21                   “(B) involving senior managers and experi-  
22                   enced staff of the Food and Drug Administra-  
23                   tion, as appropriate, in a collaborative, cross-  
24                   disciplinary review of the method of manufac-  
25                   turing, as applicable.

1           “(2) EVALUATION AND DESIGNATION.—Not  
2 later than 180 calendar days after the receipt of a  
3 request under paragraph (1), the Secretary shall de-  
4 termine whether to designate such method of manu-  
5 facturing as an advanced manufacturing technology,  
6 in a particular context of use, based on the data and  
7 information submitted under paragraph (1) and the  
8 criteria described in subsection (b).

9           “(d) REVIEW OF ADVANCED MANUFACTURING  
10 TECHNOLOGIES.—If the Secretary designates a method of  
11 manufacturing as an advanced manufacturing technology,  
12 the Secretary shall—

13           “(1) expedite the development and review of an  
14 application submitted under section 505 of this Act  
15 or section 351 of the Public Health Service Act, in-  
16 cluding supplemental applications, for drugs that are  
17 manufactured using a designated advanced manufac-  
18 turing technology; and

19           “(2) allow the holder of an advanced technology  
20 designation, or a person authorized by the advanced  
21 manufacturing technology designation holder, to ref-  
22 erence or rely upon, in an application submitted  
23 under section 505 of this Act or section 351 of the  
24 Public Health Service Act, including a supplemental  
25 application, data and information about the des-

1       ignated advanced manufacturing technology for use  
2       in manufacturing drugs in the same context of use  
3       for which the designation was granted.

4       “(e) IMPLEMENTATION AND EVALUATION OF AD-  
5 VANCED MANUFACTURING TECHNOLOGIES PILOT.—

6           “(1) PUBLIC MEETING.—The Secretary shall  
7       publish in the Federal Register a notice of a public  
8       meeting, to be held not later than 180 days after the  
9       date of enactment of this section, to discuss, and ob-  
10      tain input and recommendations from relevant  
11      stakeholders regarding—

12           “(A) the goals and scope of the pilot pro-  
13      gram, and a suitable framework, procedures,  
14      and requirements for such program; and

15           “(B) ways in which the Food and Drug  
16      Administration will support the use of advanced  
17      manufacturing technologies and other innova-  
18      tive manufacturing approaches for drugs.

19      “(2) PILOT PROGRAM GUIDANCE.—

20           “(A) IN GENERAL.—The Secretary shall—

21           “(i) not later than 180 days after the  
22      public meeting under paragraph (1), issue  
23      draft guidance regarding the goals and im-  
24      plementation of the pilot program under  
25      this section; and

1           “(ii) not later than 2 years after the  
2           date of enactment of this section, issue  
3           final guidance regarding the implementa-  
4           tion of such program.

5           “(B) CONTENT.—The guidance described  
6           in subparagraph (A) shall address—

7           “(i) the process by which a person  
8           may request a designation under sub-  
9           section (b);

10          “(ii) the data and information that a  
11          person requesting such a designation is re-  
12          quired to submit under subsection (c), and  
13          how the Secretary intends to evaluate such  
14          submissions;

15          “(iii) the process to expedite the de-  
16          velopment and review of applications under  
17          subsection (d); and

18          “(iv) the criteria described in sub-  
19          section (b) for eligibility for such a des-  
20          ignation.

21          “(3) REPORT.—Not later than 3 years after the  
22          date of enactment of this section and annually there-  
23          after, the Secretary shall publish on the website of  
24          the Food and Drug Administration and submit to  
25          the Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on En-  
2 ergy and Commerce of the House of Representatives  
3 a report containing a description and evaluation of  
4 the pilot program being conducted under this sec-  
5 tion, including the types of innovative manufacturing  
6 approaches supported under the program. Such re-  
7 port shall include the following:

8 “(A) The number of persons that have re-  
9 quested designations and that have been grant-  
10 ed designations.

11 “(B) The number of methods of manufac-  
12 turing that have been the subject of designation  
13 requests and that have been granted designa-  
14 tions.

15 “(C) The average number of calendar days  
16 for completion of evaluations under subsection  
17 (c)(2).

18 “(D) An analysis of the factors in data  
19 submissions that result in determinations to  
20 designate and not to designate after evaluation  
21 under subsection (c)(2).

22 “(E) The number of applications received  
23 under section 505 of this Act or section 351 of  
24 the Public Health Service Act, including supple-  
25 mental applications, that have included an ad-

1           vanded manufacturing technology designated  
2           under this section, and the number of such ap-  
3           plications approved.

4           “(f) SUNSET.—The Secretary—

5           “(1) may not consider any requests for designa-  
6           tion submitted under subsection (c) after October 1,  
7           2029; and

8           “(2) may continue all activities under this sec-  
9           tion with respect to advanced manufacturing tech-  
10          nologies that were designated pursuant to subsection  
11          (d) prior to such date, if the Secretary determines  
12          such activities are in the interest of the public  
13          health.”.

14   **SEC. 519. TECHNICAL CORRECTIONS.**

15          (a) TECHNICAL CORRECTIONS TO THE CARES  
16    ACT.—Division A of the CARES Act (Public Law 116–  
17    136) is amended—

18           (1) in section 3111(1), by striking “in para-  
19           graph (1)” and inserting “in the matter preceding  
20           paragraph (1)”;

21           (2) in section 3112(d)(1), by striking “and sub-  
22           paragraphs (A) and (B)” and inserting “as subpara-  
23           graphs (A) and (B)”;

1           (3) in section 3112(e), by striking “Federal  
2           Food, Drug, Cosmetic Act” and inserting “Federal  
3           Food, Drug, and Cosmetic Act”.

4           (b) TECHNICAL CORRECTIONS TO THE FEDERAL  
5           FOOD, DRUG, AND COSMETIC ACT RELATED TO THE  
6           CARES ACT.—

7           (1) SECTION 506C.—Section 506C(a) of the  
8           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9           356c(a)) is amended, in the flush text at the end, by  
10          striking the second comma after “in the United  
11          States”.

12          (2) EFFECTIVE DATE.—The amendment made  
13          by paragraph (1) shall take effect as if included in  
14          section 3112 of division A of the CARES Act (Pub-  
15          lic Law 116–136).

16          (c) OTHER TECHNICAL CORRECTION TO THE FED-  
17          ERAL FOOD, DRUG, AND COSMETIC ACT.—Section  
18          505B(f)(6)(I) of the Federal Food, Drug, and Cosmetic  
19          Act (21 U.S.C. 355c(f)(6)(I)) is amended by striking  
20          “subsection (a)(3)(B)” and inserting “subsection  
21          (a)(4)(C)”.

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