

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “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

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- 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. Advisory Committee to the Director of the Centers for Disease Control and Prevention.
- Sec. 105. Public health and medical preparedness and response coordination.
- Sec. 106. Strengthening public health communication.
- Sec. 107. 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.
- Sec. 115. Consideration of unique challenges in noncontiguous States and territories.

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. Public health data transparency.
- Sec. 216. GAO report on public health preparedness, response, and recovery data capabilities.

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.
- Sec. 227. Assessing barriers to additional training.
- Sec. 228. Leadership exchange pilot for public health and medical preparedness and response positions at the Department of Health and Human Services.

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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.
- Sec. 234. Supporting laboratory capacity and international collaboration to address antimicrobial resistance.
- Sec. 235. One Health framework.
- Sec. 236. Supporting children during public health emergencies.

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.
- Sec. 305. National Academies of Sciences, Engineering, and Medicine study on natural immunity in relation to the COVID-19 pandemic.

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 and addressing other national security risks related to research.
- 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.

Subtitle D—Advanced Research Projects Authority for Health

- Sec. 331. Advanced Research Projects Authority for Health.

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.
- Sec. 410. Study on incentives for domestic production of generic medicines.

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

1 United States to the COVID–19 Pandemic” (referred to
2 in this section as the “Task Force”).

3 (b) PURPOSES.—The purposes of the Task Force are
4 to—

5 (1) examine, assess, and report upon the
6 United States’ preparedness for, and response to,
7 the COVID–19 pandemic, including—

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

10 (B) the ongoing Federal, State, local, and
11 territorial responses in the United States, in-
12 cluding the activities, policies, and decisions of
13 the Trump Administration and the Biden Ad-
14 ministration;

15 (C) the impact of the pandemic on public
16 health and health care systems; and

17 (D) the initial outbreak in Wuhan, China,
18 including efforts to determine the potential
19 causes for the emergence of the SARS–CoV–2
20 virus, and Federal actions to mitigate its spread
21 internationally;

22 (2) build upon existing or ongoing evaluations
23 and avoid unnecessary duplication, by reviewing the
24 findings, conclusions, and recommendations of other
25 appropriate task forces, committees, commissions, or

1 entities established by other public or nonprofit pri-
2 vate entities related to the United States' prepared-
3 ness for, and response to, the COVID-19 pandemic;

4 (3) identify gaps in public health preparedness
5 and medical response policies, processes, and activi-
6 ties, including disparities in COVID-19 infection
7 and mortality rates among people of color, older
8 adults, people with disabilities, and other vulnerable
9 or at-risk groups, and how such gaps impacted the
10 ability of the United States to respond to the
11 COVID-19 pandemic; and

12 (4) submit a report to the President and to
13 Congress on its findings, conclusions, and rec-
14 ommendations to improve the United States' pre-
15 paredness for, and response to, future public health
16 emergencies, including a public health emergency re-
17 sulting from an emerging infectious disease.

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

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

21 (A) 1 member shall be appointed by the
22 majority leader of the Senate;

23 (B) 1 member shall be appointed by the
24 minority leader of the Senate;

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

4 (D) 2 members shall be appointed by the
5 ranking member of the Committee on Health,
6 Education, Labor, and Pensions of the Senate;

7 (E) 1 member shall be appointed by the
8 Speaker of the House of Representatives;

9 (F) 1 member shall be appointed by the
10 minority leader of the House of Representa-
11 tives;

12 (G) 2 members shall be appointed by the
13 chair of the Committee on Energy and Com-
14 merce of the House of Representatives; and

15 (H) 2 members shall be appointed by the
16 ranking member of the Committee on Energy
17 and Commerce of the House of Representatives.

18 (2) CHAIR AND VICE CHAIR.—Not later than 30
19 days after the date on which all members of the
20 Task Force are appointed under paragraph (1), such
21 members shall meet to elect a Chair and Vice Chair
22 from among such members. The Chair and Vice
23 Chair shall each be elected to serve upon an affirma-
24 tive vote from 8 members of the Task Force. The

1 Chair and Vice Chair shall not be registered mem-
2 bers of the same political party.

3 (3) QUALIFICATIONS.—

4 (A) POLITICAL PARTY AFFILIATION.—Not
5 more than 6 members of the Task Force shall
6 be registered members of the same political
7 party.

8 (B) NONGOVERNMENTAL APPOINTEES.—
9 An individual appointed to the Task Force may
10 not be an officer or employee of the Federal
11 Government or any State, local, Tribal, or terri-
12 torial government.

13 (C) QUALIFICATIONS.—It is the sense of
14 Congress that individuals appointed to the Task
15 Force should be highly qualified citizens of the
16 United States. Members appointed under para-
17 graph (1) may include individuals with expertise
18 in—

19 (i) public health, health disparities
20 and at-risk populations, medicine, and re-
21 lated fields;

22 (ii) State, local, Tribal, or territorial
23 government, including public health and
24 medical preparedness and response and
25 emergency management, workplace health

1 and safety, and other relevant public ad-
2 ministration;

3 (iii) research regarding, or the devel-
4 opment, manufacturing, distribution, and
5 regulation of, medical products;

6 (iv) national security and foreign rela-
7 tions, including global health; and

8 (v) commerce, including transpor-
9 tation, supply chains, and small business.

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

14 (5) MEETINGS.—The Task Force shall meet
15 and begin the operations of the Task Force as soon
16 as practicable. After its initial meeting, the Task
17 Force shall meet upon the call of the Chair and Vice
18 Chair or 8 of its members.

19 (6) QUORUM; VACANCIES.—

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

22 (B) VACANCIES.—Any vacancy in the Task
23 Force shall not affect its powers, but may be
24 filled in the same manner in which the original
25 appointment was made, or, if the deadline

1 under paragraph (4) has expired, may be filled
2 by a member appointed by any person with ap-
3 pointing power under paragraph (1) who is of
4 the same political party and chamber of Con-
5 gress as the person with appointing power des-
6 ignated under paragraph (1) to make the ap-
7 pointment.

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

10 (1) conduct a review that—

11 (A) examines the initial outbreak of the
12 SARS-CoV-2 virus in Wuhan, China, includ-
13 ing—

14 (i) engaging with willing partner gov-
15 ernments and global experts;

16 (ii) seeking access to relevant records;

17 and

18 (iii) examining the potential causes of
19 the emergence and source of the virus;

20 (B) examines the United States' prepara-
21 tion for, and response to, the COVID-19 pan-
22 demic, including—

23 (i) relevant laws, policies, regulations,
24 and processes that were in place prior to,
25 or put into place during, the public health

1 emergency declared by the Secretary of
2 Health and Human Services under section
3 319 of the Public Health Service Act (42
4 U.S.C. 247d) with respect to COVID–19,
5 including any that are put into place re-
6 lated to such public health emergency after
7 the date of enactment of this Act and prior
8 to the issuance of the final report pursuant
9 to subsection (j)(2);

10 (ii) relevant actions taken by, and co-
11 ordination between, Federal, State, local,
12 Tribal, and territorial governments, non-
13 governmental organizations, and inter-
14 national organizations on preparedness and
15 response efforts, including coordination be-
16 tween governments and other public and
17 private entities, during the—

18 (I) initial response in the United

19 States;

20 (II) response during the Trump

21 Administration; and

22 (III) ongoing response during the

23 Biden Administration;

24 (iii) communication of public health
25 and scientific information related to the

1 COVID–19 pandemic, including processes
2 for the development, approval, and dis-
3 semination of Federal public health and
4 other relevant public health or scientific
5 guidance;

6 (iv) actions taken to support the de-
7 velopment, manufacturing, and distribution
8 of medical countermeasures and related
9 medical supplies to prevent, detect, and
10 treat COVID–19; and

11 (C) may include assessments relating to—

12 (i) the capacity and capabilities of
13 Federal, State, local, Tribal, and territorial
14 governments to respond to the COVID–19
15 pandemic;

16 (ii) the capacity and capabilities of
17 health care facilities, including nursing
18 homes and other long-term care facilities,
19 and the health care workforce to respond
20 to the COVID–19 pandemic;

21 (iii) medical countermeasure research
22 and development and the supply chains of
23 medical products necessary to respond to
24 the COVID–19 pandemic;

1 (iv) international preparedness for
2 and response to COVID–19, and Federal
3 decision-making processes related to new
4 global health threats;

5 (v) containment and mitigation meas-
6 ures related to domestic and international
7 travel in response to COVID–19; and

8 (vi) the impact of the COVID–19 pan-
9 demic and related mitigation efforts on
10 hard-to-reach and at-risk or underserved
11 populations, including related health dis-
12 parities; and;

13 (2) identify, review, and evaluate the lessons
14 learned from the COVID–19 pandemic, including ac-
15 tivities to prepare for, and respond to, future poten-
16 tial pandemics and related public health emer-
17 gencies; and

18 (3) submit to the President and Congress such
19 reports as are required by this Act containing such
20 findings, conclusions, and recommendations as the
21 Task Force shall determine.

22 (e) POWERS OF TASK FORCE.—

23 (1) HEARINGS.—The Task Force may—

24 (A) hold such hearings and sit and act at
25 such times and places, take such testimony, re-

1 Force, and may be served by any person
2 designated by the Chair or by a member
3 designated by agreement of the majority of
4 the Task Force.

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

17 (3) CONTRACTING.—The Task Force may, to
18 such extent and in such amounts as are provided in
19 appropriation Acts, enter into contracts to enable
20 the Task Force to discharge its duties under this
21 Act.

22 (4) INFORMATION FROM FEDERAL AGENCIES.—

23 (A) IN GENERAL.—The Task Force may
24 access from any executive department, bureau,
25 agency, board, commission, office, independent

1 establishment, or instrumentality of the Federal
2 Government, such information, documents, sug-
3 gestions, estimates, and statistics as the Task
4 Force considers necessary to carry out this sec-
5 tion.

6 (B) PROVISION OF INFORMATION.—On
7 written request of the Chair, each department,
8 bureau, agency, board, commission, office, inde-
9 pendent establishment, or instrumentality shall,
10 to the extent authorized by law, provide such
11 information to the Task Force.

12 (C) RECEIPT, HANDLING, STORAGE, AND
13 DISSEMINATION.—Information shall only be re-
14 ceived, handled, stored, and disseminated by
15 members of the Task Force and its staff con-
16 sistent with all applicable statutes, regulations,
17 and executive orders.

18 (5) ASSISTANCE FROM FEDERAL AGENCIES.—

19 (A) GENERAL SERVICES ADMINISTRA-
20 TION.—On request of the Chair and Vice Chair,
21 the Administrator of General Services Adminis-
22 tration shall provide to the Task Force, on a re-
23 imburseable basis, administrative support and
24 other assistance necessary for the Task Force
25 to carry out its duties.

1 (B) OTHER DEPARTMENTS AND AGEN-
2 CIES.—In addition to the assistance provided
3 for in subparagraph (A), departments and
4 agencies of the United States may provide to
5 the Task Force such assistance as such depart-
6 ments and agencies may determine advisable
7 and as authorized by law.

8 (6) DONATIONS.—The Task Force may accept,
9 use, and dispose of gifts or donations of services or
10 property. Not later than 5 days after the acceptance
11 of a donation under this subsection, the Task Force
12 shall publicly disclose—

13 (A) the name of the entity that provided
14 such donation;

15 (B) the service or property provided
16 through such donation;

17 (C) the value of such donation; and

18 (D) how the Task Force plans to use such
19 donation.

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

24 (f) NON-APPLICABILITY OF FEDERAL ADVISORY
25 COMMITTEE ACT.—

1 (1) IN GENERAL.—The Federal Advisory Com-
2 mittee Act (5 U.S.C. App.) shall not apply to the
3 Task Force.

4 (2) PUBLIC MEETINGS AND RELEASE OF PUB-
5 LIC VERSIONS OF REPORTS.—The Task Force
6 shall—

7 (A) hold public hearings and meetings to
8 the extent appropriate; and

9 (B) release public versions of the reports
10 required under paragraph (1) and (2) of sub-
11 section (j).

12 (3) PUBLIC HEARINGS.—Any public hearings of
13 the Task Force shall be conducted in a manner con-
14 sistent with the protection of information provided
15 to or developed for or by the Task Force as required
16 by any applicable statute, regulation, or Executive
17 order.

18 (g) STAFF OF TASK FORCE.—

19 (1) IN GENERAL.—

20 (A) APPOINTMENT AND COMPENSATION.—

21 The Chair of the Task Force, in agreement
22 with the Vice Chair, in accordance with rules
23 agreed upon by the Task Force, may appoint
24 and fix the compensation of a staff director and
25 such other personnel as may be necessary to en-

1 able the Task Force to carry out its functions,
2 without regard to the provisions of title 5,
3 United States Code, governing appointments in
4 the competitive service, and without regard to
5 the provisions of chapter 51 and subchapter III
6 of chapter 53 of such title relating to classifica-
7 tion and General Schedule pay rates, except
8 that no rate of pay fixed under this subsection
9 may exceed the equivalent of that payable for a
10 position at level V of the Executive Schedule
11 under section 5316 of title 5, United States
12 Code.

13 (B) PERSONNEL AS FEDERAL EMPLOY-
14 EES.—

15 (i) IN GENERAL.—The staff director
16 and any personnel of the Task Force who
17 are employees shall be employees under
18 section 2105 of title 5, United States
19 Code, for purposes of chapters 63, 81, 83,
20 84, 85, 87, 89, and 90 of that title.

21 (ii) MEMBERS OF TASK FORCE.—
22 Clause (i) shall not be construed to apply
23 to members of the Task Force.

24 (2) DETAILEES.—Upon request of the Chair
25 and Vice Chair of the Task Force, the head of any

1 executive department, bureau, agency, board, com-
2 mission, office, independent establishment, or instru-
3 mentality of the Federal Government employee may
4 detail, without reimbursement, any of its personnel
5 to the Task Force to assist in carrying out its duties
6 under this section. Any such detailee shall be with-
7 out interruption or loss of civil service status or
8 privilege.

9 (3) CONSULTANT SERVICES.—The Task Force
10 is authorized to procure the services of experts and
11 consultants in accordance with section 3109 of title
12 5, United States Code, but at rates not to exceed the
13 daily rate paid a person occupying a position at level
14 IV of the Executive Schedule under section 5315 of
15 title 5, United States Code.

16 (h) COMPENSATION AND TRAVEL EXPENSES.—Each
17 member of the Task Force shall serve without compensa-
18 tion, but shall receive travel expenses, including per diem
19 in lieu of subsistence, at rates authorized for an employee
20 of an agency under subchapter I of chapter 57 of title
21 5, United States Code.

22 (i) SECURITY CLEARANCES FOR TASK FORCE MEM-
23 BERS AND STAFF.—The appropriate Federal agencies or
24 departments shall cooperate with the Task Force in expe-
25 ditiously providing to the Task Force members and staff

1 appropriate security clearances, consistent with existing
2 procedures and requirements. No person shall be provided
3 with access to classified information under this section
4 without the appropriate security clearances.

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

6 (1) INTERIM REPORT.—Not later than 180
7 days after the date of enactment of this Act, the
8 Task Force shall submit to the President, the Com-
9 mittee on Health, Education, Labor, and Pensions
10 of the Senate, and the Committee on Energy and
11 Commerce of the House of Representatives an in-
12 terim report containing such findings, conclusions,
13 and recommendations as have been agreed to by 8
14 members of the Task Force. Such interim report
15 shall be made available online in a manner that does
16 not compromise national security.

17 (2) FINAL REPORT.—

18 (A) IN GENERAL.—Not later than 18
19 months after the date on which the last member
20 of the Task Force is appointed, the Task Force
21 shall submit to the President, the Committee on
22 Health, Education, Labor, and Pensions of the
23 Senate, and the Committee on Energy and
24 Commerce of the House of Representatives a
25 final report containing such findings, conclu-

1 sions, and recommendations as have been
2 agreed to by 8 members of the Task Force. The
3 final report shall be made available online in a
4 manner that does not compromise national se-
5 curity.

6 (B) EXTENSIONS.—

7 (i) IN GENERAL.—The submission
8 and publication of the final report, as de-
9 scribed in subparagraph (A), may be de-
10 layed by 6 months upon the agreement of
11 8 members of the Task Force.

12 (ii) NOTIFICATION.—The Task Force
13 shall notify the President, , the Committee
14 on Health, Education, Labor, and Pen-
15 sions of the Senate, the Committee on En-
16 ergy and Commerce of the House of Rep-
17 resentatives, and the public of any exten-
18 sion granted under clause (i).

19 (C) SPECIAL RULES AND CONSIDER-
20 ATIONS.—

21 (i) RULE OF CONSTRUCTION.—Noth-
22 ing in this subsection shall be construed as
23 authorizing the Task Force to publicly dis-
24 close information otherwise prohibited from
25 disclosure by law.

1 (ii) SPECIAL TIMING CONSIDER-
2 ATIONS.—Notwithstanding any other pro-
3 vision of this section, the Task Force shall
4 not publish or make available any interim
5 or final report during the during the 60-
6 day periods ending November 8, 2022, and
7 November 5, 2024.

8 (3) TERMINATION.—

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

13 (B) ADMINISTRATIVE ACTIVITIES BEFORE
14 TERMINATION.—The Task Force may use the
15 60-day period referred to in subparagraph (A)
16 for the purpose of concluding its activities, in-
17 cluding providing testimony to committees of
18 Congress concerning its reports and dissemi-
19 nating the final report.

20 (k) FUNDING.—

21 (1) AUTHORIZATION OF APPROPRIATIONS.—
22 There is authorized to be appropriated to carry out
23 this section, a total of \$3,000,000 for fiscal years
24 2023 and 2024.

1 (2) DURATION OF AVAILABILITY.—Amounts
2 made available to the Task Force under paragraph
3 (1) shall remain available until the termination of
4 the Task Force.

5 **SEC. 102. APPOINTMENT AND AUTHORITY OF THE DIREC-**
6 **TOR OF THE CENTERS FOR DISEASE CON-**
7 **TROL AND PREVENTION.**

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

11 **“SEC. 305. APPOINTMENT AND AUTHORITY OF THE DIREC-**
12 **TOR OF THE CENTERS FOR DISEASE CON-**
13 **TROL AND PREVENTION.**

14 “(a) IN GENERAL.—The Centers for Disease Control
15 and Prevention (referred to in this section as the ‘CDC’)
16 shall be headed by the Director of the Centers for Disease
17 Control and Prevention (referred to in this section as the
18 ‘Director’), who shall be appointed by the President, by
19 and with the advice and consent of the Senate. Such indi-
20 vidual shall also serve as the Administrator of the Agency
21 for Toxic Substances and Disease Registry consistent with
22 section 104(i) of the Comprehensive Environmental Re-
23 sponse, Compensation, and Liability Act. The Director
24 shall perform functions provided for in subsection (b) and
25 such other functions as the Secretary may prescribe.

1 “(b) FUNCTIONS.—The Secretary, acting through the
2 Director, shall—

3 “(1) implement and exercise applicable authori-
4 ties and responsibilities provided for in this Act or
5 other applicable law related to the investigation, de-
6 tection, identification, prevention, or control of dis-
7 eases or conditions to preserve and improve public
8 health domestically and globally and address injuries
9 and occupational and environmental hazards, as ap-
10 propriate;

11 “(2) be responsible for the overall direction of
12 the CDC and for the establishment and implementa-
13 tion of policies related to the management and oper-
14 ation of programs and activities within the CDC;

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

17 “(4) support, in consultation with the heads of
18 such centers, institutes, and offices, program coordi-
19 nation across such centers, institutes, and offices, in-
20 cluding through priority setting reviews and the de-
21 velopment of strategic plans, to reduce unnecessary
22 duplication and encourage collaboration between pro-
23 grams;

1 “(5) oversee the development, implementation,
2 and updating of the strategic plan established pursu-
3 ant to subsection (c);

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

8 “(7) communicate, including through convening
9 annual meetings, with public and private entities re-
10 garding relevant public health programs and activi-
11 ties, and, as applicable, the strategic plan estab-
12 lished pursuant to subsection (c).

13 “(c) STRATEGIC PLAN.—

14 “(1) IN GENERAL.—Not later than 1 year after
15 the date of enactment of the PREVENT Pandemics
16 Act, and at least every 4 years thereafter, the Direc-
17 tor shall develop and submit to the Committee on
18 Health, Education, Labor, and Pensions and the
19 Committee on Appropriations of the Senate and the
20 Committee on Energy and Commerce and the Com-
21 mittee on Appropriations of the House of Represent-
22 atives, and post on the website of the CDC, a coordi-
23 nated strategy to provide strategic direction and fa-
24 cilitate collaboration across the centers, institutes,

1 and offices within the CDC. Such strategy shall be
2 known as the ‘CDC Strategic Plan’.

3 “(2) REQUIREMENTS.—The CDC Strategic
4 Plan shall—

5 “(A) identify strategic priorities and objec-
6 tives related to—

7 “(i) preventing, reducing, and elimi-
8 nating the spread of communicable and
9 noncommunicable diseases or conditions,
10 and addressing injuries, and occupational
11 and environmental hazards;

12 “(ii) supporting the efforts of State,
13 local, and Tribal health departments to
14 prevent and reduce the prevalence of the
15 diseases or conditions under clause (i);

16 “(iii) containing, mitigating, and end-
17 ing disease outbreaks;

18 “(iv) enhancing global and domestic
19 public health capacity, capabilities, and
20 preparedness, including public health data,
21 surveillance, workforce, and laboratory ca-
22 pacity and safety; and

23 “(v) other priorities, as established by
24 the Director;

1 “(B) describe the capacity and capabilities
2 necessary to achieve the priorities and objec-
3 tives under subparagraph (A), and progress to-
4 wards achieving such capacity and capabilities,
5 as appropriate; and

6 “(C) include a description of how the CDC
7 Strategic Plan incorporates—

8 “(i) strategic communications;

9 “(ii) partnerships with private sector
10 entities, and State, local, and Tribal health
11 departments, and other public sector enti-
12 ties, as appropriate; and

13 “(iii) coordination with other agencies
14 and offices of the Department of Health
15 and Human Services and other Federal de-
16 partments and agencies, as appropriate.

17 “(3) USE OF PLANS.—Strategic plans developed
18 and updated by the centers, institutes, and offices of
19 the CDC shall be prepared regularly and in such a
20 manner that such plans will be informed by the CDC
21 Strategic Plan developed and updated under this
22 subsection.

23 “(d) APPEARANCES BEFORE CONGRESS.—

24 “(1) IN GENERAL.—Each fiscal year, the Direc-
25 tor shall appear before the Committee on Health,

1 Education, Labor, and Pensions of the Senate and
2 the Committee on Energy and Commerce of the
3 House of Representatives at hearings on topics such
4 as—

5 “(A) support for State, local, and Tribal
6 public health preparedness and responses to any
7 recent or ongoing public health emergency, in-
8 cluding—

9 “(i) any objectives, activities, or initia-
10 tives that have been carried out, or are
11 planned, by the Director to prepare for, or
12 respond to, the public health emergency,
13 including relevant strategic communica-
14 tions or partnerships and any gaps or chal-
15 lenges identified in such objectives, activi-
16 ties, or initiatives;

17 “(ii) any objectives and planned ac-
18 tivities for the upcoming fiscal year to ad-
19 dress gaps in, or otherwise improve, State,
20 local, and Tribal public health prepared-
21 ness; and

22 “(iii) other potential all-hazard
23 threats that the Director is preparing to
24 address;

1 “(B) activities related to public health and
2 functions of the Director described in sub-
3 section (b); and

4 “(C) updates on other relevant activities
5 supported or conducted by the CDC, or in col-
6 laboration or coordination with the heads of
7 other Federal departments, agencies, or stake-
8 holders, as appropriate.

9 “(2) CLARIFICATIONS.—

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

18 “(B) SCOPE OF REQUIREMENTS.—The re-
19 quirements of this subsection shall not be con-
20 strued to impact the appearance of other Fed-
21 eral officials or the Director at hearings of ei-
22 ther Committee described in paragraph (1) at
23 other times and for purposes other than the
24 times and purposes described in paragraph (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 the open hearing.”.

6 (b) APPLICATION.—The first sentence of section
7 305(a) of the Public Health Service Act, as added by sub-
8 section (a), shall not apply to the Director of the Centers
9 for Disease Control and Prevention who is serving on the
10 date of enactment of this Act.

11 **SEC. 103. ADDITIONAL PROVISIONS RELATED TO THE CEN-**
12 **TERS FOR DISEASE CONTROL AND PREVEN-**
13 **TION.**

14 Title III of the Public Health Service Act (42 U.S.C.
15 241 et seq.) is amended by inserting after section 305,
16 as added by section 102, the following:

17 **“SEC. 305A. ADDITIONAL PROVISIONS RELATED TO THE**
18 **CENTERS FOR DISEASE CONTROL AND PRE-**
19 **VENTION.**

20 “(a) APPOINTMENTS.—

21 “(1) IN GENERAL.—Unless otherwise specified
22 in statute, the heads of the centers or institutes of
23 the Centers for Disease Control and Prevention shall
24 be appointed by the Secretary, acting through the
25 Director of the Centers for Disease Control and Pre-

1 vention (referred to in this section as the ‘Director’).
2 Each such individual shall be appointed for 5 years.

3 “(2) REAPPOINTMENTS.—An individual ap-
4 pointed under paragraph (1) may be reappointed in
5 accordance with standards applicable to the relevant
6 appointment mechanism and as determined by the
7 Secretary. In a case in which a head is not re-
8 appointed and the successor does not take office at
9 the end of a head’s term, such head shall continue
10 to serve in such capacity until the appointment term
11 of such a successor begins.

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

15 “(4) VACANCIES.—If the position of a head of
16 a center or institute described in paragraph (1) be-
17 comes vacant before the end of a term, the head of
18 such center or institute appointed to fill the vacancy
19 shall be appointed for a 5-year term starting on the
20 date of such appointment.

21 “(5) CURRENT POSITIONS AND EXEMPTIONS.—

22 “(A) IN GENERAL.—Each such individual
23 who is serving on the date of enactment of the
24 PREVENT Pandemics Act shall be deemed to

1 be appointed for a 5-year term under this sub-
2 section beginning on such date of enactment.

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

9 “(6) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed to—

11 “(A) limit the authority of the Secretary or
12 the Director to terminate the appointment of a
13 head of a center or institute described in para-
14 graph (1) before the expiration of such individ-
15 ual’s 5-year term; or

16 “(B) alter existing law regarding reassign-
17 ment and transfer of career staff, as applicable,
18 at the end of a 5-year term of a head of a cen-
19 ter or institute.

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

1 “(b) OTHER TRANSACTIONS.—

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

9 “(2) WRITTEN DETERMINATION.—With respect
10 to a project that is expected to cost the Centers for
11 Disease Control and Prevention more than
12 \$40,000,000, the Director may exercise the author-
13 ity under paragraph (1) only upon a written deter-
14 mination by the Assistant Secretary for Financial
15 Resources of the Department of Health and Human
16 Services, that the use of such authority is essential
17 to promoting the success of the project. The author-
18 ity of the Assistant Secretary for Financial Re-
19 sources under this paragraph may not be delegated.

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

1 **SEC. 104. ADVISORY COMMITTEE TO THE DIRECTOR OF**
2 **THE CENTERS FOR DISEASE CONTROL AND**
3 **PREVENTION.**

4 Title III of the Public Health Service Act (42 U.S.C.
5 241 et seq.) is amended by inserting after section 305A,
6 as added by section 103, the following:

7 **“SEC. 305B. ADVISORY COMMITTEE TO THE DIRECTOR.**

8 “(a) IN GENERAL.—Not later than 60 days after the
9 date of the enactment of the PREVENT Pandemics Act,
10 the Secretary, acting through the Director of the Centers
11 for Disease Control and Prevention (referred to in this
12 section as the ‘Director’), shall maintain or establish an
13 advisory committee within the Centers for Disease Control
14 and Prevention to advise the Director on policy and strate-
15 gies that enable the agency to fulfill its mission.

16 “(b) FUNCTIONS AND ACTIVITIES.—The Advisory
17 Committee may—

18 “(1) make recommendations to the Director re-
19 garding ways to prioritize the activities of the agen-
20 cy in alignment with the CDC Strategic Plan re-
21 quired under section 305(c);

22 “(2) advise on ways to achieve or improve per-
23 formance metrics in relation to the CDC Strategic
24 Plan, and other relevant metrics, as appropriate;

1 “(3) provide advice and recommendations on
2 the development of the CDC Strategic Plan, and any
3 subsequent updates, as appropriate;

4 “(4) advise on grants, cooperative agreements,
5 contracts, or other transactions, as applicable;

6 “(5) provide other advice to the Director, as re-
7 quested, to fulfill duties under sections 301 and 311;
8 and

9 “(6) appoint subcommittees.

10 “(c) MEMBERSHIP.—

11 “(1) IN GENERAL.—The Advisory Committee
12 shall consist of not more than 15 non-Federal mem-
13 bers, including the Chair, to be appointed by the
14 Secretary under paragraph (3).

15 “(2) EX OFFICIO MEMBERS.—Any ex officio
16 members of the Advisory Council may consist of—

17 “(A) the Secretary;

18 “(B) the Assistant Secretary for Health;

19 “(C) the Director; and

20 “(D) such additional officers or employees
21 of the United States as the Secretary deter-
22 mines necessary for the advisory committee to
23 effectively carry out its functions.

1 “(3) APPOINTED MEMBERS.—Individuals shall
2 be appointed to the Advisory Committee under para-
3 graph (1) as follows:

4 “(A) Twelve of the members shall be ap-
5 pointed by the Director from among the leading
6 representatives of the health disciplines (includ-
7 ing public health, global health, health dispari-
8 ties, biomedical research, public health pre-
9 paredness, and other fields, as applicable) rel-
10 evant to the activities of the agency or center,
11 as applicable.

12 “(B) Three of the members may be ap-
13 pointed by the Secretary from the general pub-
14 lic and may include leaders in fields of innova-
15 tion, public policy, public relations, law, eco-
16 nomics, or management.

17 “(4) COMPENSATION.—Ex officio members of
18 the Advisory Council who are officers or employees
19 of the United States shall not receive any compensa-
20 tion for service on the advisory committee. The re-
21 maining members of the advisory committee may re-
22 ceive, for each day (including travel time) they are
23 engaged in the performance of the functions of the
24 advisory committee, compensation at rates not to ex-
25 ceed the daily equivalent to the annual rate of basic

1 pay for level III of the Executive Schedule under
2 section 5314 of title 5, United States Code.

3 “(5) TERMS OF OFFICE.—

4 “(A) IN GENERAL.—The term of office of
5 a member of the advisory committee appointed
6 under paragraph (3) shall be 4 years, except
7 that any member appointed to fill a vacancy for
8 an unexpired term shall serve for the remainder
9 of such term. The Secretary shall make ap-
10 pointments to the advisory committee in such a
11 manner as to ensure that the terms of the
12 members not all expire in the same year. A
13 member of the advisory committee may serve
14 after the expiration of such member’s term
15 until a successor has been appointed and taken
16 office.

17 “(B) REAPPOINTMENTS.—A member who
18 has been appointed to the advisory committee
19 for a term of 4 years may not be reappointed
20 to the advisory committee during the 2-year pe-
21 riod beginning on the date on which such 4-
22 year term expired.

23 “(C) TIME FOR APPOINTMENT.—If a va-
24 cancy occurs in the advisory committee among
25 the members appointed under paragraph (3),

1 the Secretary shall make an appointment to fill
2 such vacancy within 90 days from the date the
3 vacancy occurs.

4 “(d) CHAIR.—The Secretary shall select a member
5 of the advisory committee to serve as the Chair of the com-
6 mittee. The Secretary may so select an individual from
7 among the appointed members. The term of office of the
8 chair shall be 2 years.

9 “(e) MEETINGS.—The advisory committee shall meet
10 at the call of the Chair or upon request of the Director,
11 but in no event less than 2 times during each fiscal year.

12 “(f) EXECUTIVE SECRETARY AND STAFF.—The Di-
13 rector shall designate a member of the staff of the agency
14 to serve as the executive secretary of the advisory com-
15 mittee. The Director shall make available to the advisory
16 committee such staff, information, and other assistance as
17 it may require to carry out its functions. The Director
18 shall provide orientation and training for new members
19 of the advisory committee to provide for their effective
20 participation in the functions of the advisory committee.”.

21 **SEC. 105. PUBLIC HEALTH AND MEDICAL PREPAREDNESS**

22 **AND RESPONSE COORDINATION.**

23 (a) PUBLIC HEALTH EMERGENCY FUND.—Section
24 319(b) of the Public Health Service Act (42 U.S.C.
25 247d(b)) is amended—

1 (1) in paragraph (2)—

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

4 (B) by redesignating subparagraph (F) as
5 subparagraph (G); and

6 (C) by inserting after subparagraph (E),
7 the following:

8 “(F) support the initial deployment and
9 distribution of contents of the Strategic Na-
10 tional Stockpile, as appropriate; and”;

11 (2) by amending paragraph (3)(A) to read as
12 follows:

13 “(A) the expenditures made from the Pub-
14 lic Health Emergency Fund in such fiscal year,
15 including—

16 “(i) the amount obligated;

17 “(ii) the recipient or recipients of such
18 obligated funds;

19 “(iii) the specific response activities
20 such obligated funds will support; and

21 “(iv) the declared or potential public
22 health emergency for which such funds
23 were obligated; and”.

24 (b) IMPROVING PUBLIC HEALTH AND MEDICAL PRE-
25 PAREDNESS AND RESPONSE COORDINATION.—

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

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

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

19 (A) in paragraph (1), by inserting “and,
20 consistent with the National Response Frame-
21 work and other applicable provisions of law, as-
22 sist the Secretary in carrying out the functions
23 under section 2801” before the period; and

24 (B) in paragraph (4)—

1 (i) in subparagraph (E) by striking
2 “the actions necessary to overcome these
3 obstacles.” and inserting “recommend ac-
4 tions necessary to overcome these obsta-
5 cles, such as—

6 “(i) improving coordination with rel-
7 evant Federal officials;

8 “(ii) partnering with other public or
9 private entities to leverage capabilities
10 maintained by such entities, as appropriate
11 and consistent with this subsection; and

12 “(iii) coordinating efforts to support
13 or establish new capabilities, as appro-
14 priate.”;

15 (ii) in subparagraph (G)—

16 (I) by redesignating clauses (i)
17 and (ii) as subclauses (I) and (II) and
18 adjusting the margins accordingly;

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

21 (aa) by inserting “each year,
22 including national-level and
23 State-level full-scale exercises not
24 less than once every 4 years”
25 after “operational exercises”; and

1 (bb) by striking “exercises
2 based on—” and inserting “exer-
3 cises—

4 “(i) based on”;

5 (III) by striking the period and
6 inserting a semicolon; and

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

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

20 “(iii) conducted in coordination with
21 State and local health officials.”; and

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

24 “(J) MEDICAL PRODUCT AND SUPPLY CA-
25 PACITY PLANNING.—Coordinate efforts within

1 the Department of Health and Human Services
2 to support—

3 “(i) preparedness for medical product
4 and medical supply needs directly related
5 to responding to chemical, biological, radio-
6 logical, or nuclear threats, including
7 emerging infectious diseases, and incidents
8 covered by the National Response Frame-
9 work, including—

10 “(I) sharing information, includ-
11 ing with appropriate stakeholders, re-
12 lated to the anticipated need for, and
13 availability of, such products and sup-
14 plies during such responses;

15 “(II) supporting activities, which
16 may include public-private partner-
17 ships, to maintain capacity of medical
18 products and medical supplies, as ap-
19 plicable and appropriate; and

20 “(III) planning for potential
21 surges in medical supply needs for
22 purposes of a response to such a
23 threat; and

24 “(ii) situational awareness with re-
25 spect to anticipated need for, and avail-

1 ability of, such medical products and med-
2 ical supplies within the United States dur-
3 ing a response to such a threat.”.

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

8 “(g) APPEARANCES BEFORE CONGRESS.—

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

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

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

23 “(C) support for State, local, and Tribal
24 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 and the Committee on
14 Appropriations of the Senate and the Committee on En-
15 ergy and Commerce and the Committee on Appropriations
16 of the House of Representatives, containing—

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

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

24 “(3) the state of public health preparedness and
25 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 respondi-
4 ng 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. 106. 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,
6 including consideration of the delivery of such
7 information in a manner that takes into ac-
8 count the range of communication needs of the
9 intended recipients, including at-risk individ-
10 uals, to improve such communication between
11 Federal, State, local, and Tribal health officials,
12 and, as appropriate, to address misinformation
13 during public health emergencies, including
14 strategies to—

15 “(i) identify the most effective meth-
16 ods for the dissemination of information
17 during a public health emergency, with
18 consideration of the needs of at-risk popu-
19 lations;

20 “(ii) determine best practices and
21 communicate information to populations
22 that may be impacted by such misinforma-
23 tion; and

24 “(iii) adapt approaches for the dis-
25 semination of information, as appropriate,

1 to address emerging trends related to mis-
2 information.

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

5 “(A) appropriate Federal officials, ap-
6 pointed by the Secretary, who shall serve as
7 nonvoting members; and

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

17 “(4) DISSEMINATION.—The Secretary shall re-
18 view the recommendations of the Advisory Com-
19 mittee and, not later than 180 days after receipt of
20 the report under paragraph (2), shall submit to the
21 Committee on Health, Education, Labor, and Pen-
22 sions of the Senate and the Committee on Energy
23 and Commerce of the House of Representatives a re-
24 port describing any actions planned by the Secretary
25 related to the communication and dissemination of

1 scientific and evidence-based public health informa-
2 tion, including addressing misinformation, as appro-
3 priate.

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

7 **SEC. 107. OFFICE OF PANDEMIC PREPAREDNESS AND RE-**
8 **SPONSE POLICY.**

9 (a) **IN GENERAL.**—There is established in the Execu-
10 tive Office of the President an Office of Pandemic Pre-
11 paredness and Response Policy (referred to in this section
12 as the “Office”), which shall be headed by a Director (re-
13 ferred to in this section as the “Director”) appointed by
14 the President and who shall be compensated at the rate
15 provided for level II of the Executive Schedule in section
16 5313 of title 5, United States Code. The President is au-
17 thorized to appoint not more than 2 Associate Directors,
18 who shall be compensated at a rate not to exceed that pro-
19 vided for level III of the Executive Schedule in section
20 5314 of such title. Associate Directors shall perform such
21 functions as the Director may prescribe.

22 (b) **FUNCTIONS OF THE DIRECTOR.**—The primary
23 function of the Director is to provide advice, within the
24 Executive Office of the President, on policy related to pre-
25 paredness for, and response to, pandemic and other bio-

1 logical threats that may impact national security, and sup-
2 port strategic coordination and communication with re-
3 spect to relevant activities across the Federal Government.

4 In addition to such other functions and activities as the
5 President may assign, the Director, consistent with appli-
6 cable laws and the National Response Framework, shall—

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

12 (2) coordinate Federal activities to prepare for,
13 and respond to, pandemic and other biological
14 threats, by—

15 (A) providing strategic direction to the
16 heads of applicable Federal departments, agen-
17 cies, and offices, including—

18 (i) the establishment, implementation,
19 prioritization, and assessment of policy
20 goals and objectives across the Executive
21 Office of the President and such depart-
22 ments, agencies, and offices;

23 (ii) supporting the assessment and
24 clarification of roles and responsibilities re-
25 lated to such Federal activities; and

1 (iii) supporting the development and
2 implementation of metrics and perform-
3 ance measures to evaluate the extent to
4 which applicable activities meet such goals
5 and objectives;

6 (B) providing, in consultation with the
7 Secretary of Health and Human Services and
8 the heads of other relevant Federal depart-
9 ments, agencies, and offices, leadership with re-
10 spect to the National Biodefense Strategy and
11 related activities pursuant to section 1086 of
12 the National Defense Authorization Act for Fis-
13 cal Year 2017 (6 U.S.C. 104) and section 363
14 of the William M. (Mac) Thornberry National
15 Defense Authorization Act for Fiscal Year 2021
16 (6 U.S.C. 105);

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

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

1 (E) overseeing coordination of Federal ef-
2 forts to prepare for and support the production,
3 supply, and distribution of relevant medical
4 products and supplies during a response to a
5 pandemic or other biological threat, as applica-
6 ble and appropriate, including supporting Fed-
7 eral efforts to assess any relevant vulnerabilities
8 in the supply chain of such products and sup-
9 plies;

10 (F) overseeing coordination of Federal ef-
11 forts for the basic and advanced research, de-
12 velopment, manufacture, and procurement of
13 medical countermeasures for such threats, in-
14 cluding by—

15 (i) serving, with the Secretary of
16 Health and Human Services, as co-Chair
17 of the Public Health Emergency Medical
18 Countermeasures Enterprise established
19 pursuant to section 2811–1 of the Public
20 Health Service Act (42 U.S.C. 300hh–
21 10a);

22 (ii) promoting coordination between
23 the medical countermeasure research, de-
24 velopment, and procurement activities of
25 respective Federal departments and agen-

1 cies, including to advance the discovery
2 and development of new medical products
3 and technologies;

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

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

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

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

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

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

1 and provide recommendations, as appropriate, to the
2 President;

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

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

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

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

1 providing the Director such information as the Director
2 determines necessary to carry out the functions of the Di-
3 rector under this section.

4 (d) PREPAREDNESS OUTLOOK REPORT.—

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

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

1 (e) INTERDEPARTMENTAL WORKING GROUP.—The
2 Director shall lead an interdepartmental working group
3 that will meet on a regular basis to evaluate national bio-
4 security and pandemic preparedness issues and make rec-
5 ommendations to the heads of applicable Federal depart-
6 ments, agencies and offices. The working group shall con-
7 sist of representatives from—

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

10 (2) the Department of Health and Human
11 Services;

12 (3) the Department of Homeland Security;

13 (4) the Department of Defense;

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

15 (6) other Federal Departments and agencies.

16 (f) INDUSTRY LIAISON.—

17 (1) IN GENERAL.—Not later than 10 days after
18 the initiation of a Federal response to a pandemic
19 or other biological threat that may pose a risk to na-
20 tional security, the Director shall appoint an Indus-
21 try Liaison within the Office of Pandemic Prepared-
22 ness and Response Policy to serve until the termi-
23 nation of such response.

24 (2) ACTIVITIES.—The Industry Liaison shall—

1 (A) not later than 20 days after the initi-
2 ation of such response, identify affected indus-
3 tries and develop a plan to regularly commu-
4 nicate with, and receive input from, affected in-
5 dustries; and

6 (B) work with relevant Federal depart-
7 ments and agencies to support information
8 sharing and coordination with industry stake-
9 holders.

10 (g) ADDITIONAL FUNCTIONS OF THE DIRECTOR.—

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

13 (1) shall—

14 (A) serve as a member of the Domestic
15 Policy Council and the National Security Coun-
16 cil;

17 (B) serve as a member of the Intergovern-
18 mental Science, Engineering, and Technology
19 Advisory Panel under section 205(b) of the Na-
20 tional Science and Technology Policy, Organiza-
21 tion, and Priorities Act of 1976 (42 U.S.C.
22 6614(b)) and the Federal Coordinating Council
23 for Science, Engineering and Technology under
24 section 401 of such Act (42 U.S.C. 6651);

1 (C) consult with State, Tribal, local, and
2 territorial governments, industry, academia,
3 professional societies, and other stakeholders,
4 as appropriate;

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

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

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

20 (h) STAFFING AND DETAILEES.—In carrying out
21 functions under this section, the Director may—

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

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

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

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

17 (i) **PREPAREDNESS REVIEW AND REPORT.**—The Di-
18 rector, in consultation with the heads of applicable Federal
19 departments, agencies, and offices, shall—

20 (1) not later than 1 year after the date of en-
21 actment of this Act, conduct a review of applicable
22 Federal strategies, policies, procedures, and after-ac-
23 tion reports to identify gaps and inefficiencies re-
24 lated to pandemic preparedness and response;

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

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

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

13 (C) the findings of the review conducted
14 under paragraph (1);

15 (D) any barriers or limitations related to
16 addressing such findings;

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

22 (F) current and planned activities to sup-
23 port the development of expertise within the
24 Federal Government pursuant to subsection
25 (b)(3); and

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

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

9 (k) CONFORMING AMENDMENTS.—

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

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

17 (B) in subsection (b)—

18 (i) by redesignating paragraph (10) as
19 paragraph (11); and

20 (ii) by inserting after paragraph (9)
21 the following:

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

24 (2) Section 101(c)(1) of the National Security
25 Act of 1947 (50 U.S.C. 3021(c)(1)) is amended by

1 inserting “the Director of the Office of Pandemic
2 Preparedness and Response Policy” after “Treas-
3 ury,”.

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

7 (A) in section 205(b)(2) (42 U.S.C.
8 6614(b)(2))—

9 (i) by striking “and (C)” and insert-
10 ing “(C)”; and

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

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

19 **Subtitle B—State and Local**
20 **Readiness**

21 **SEC. 111. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
22 **SECURITY.**

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

1 (1) in subparagraph (A)—

2 (A) in clause (vii), by inserting “during
3 and” before “following a public health emer-
4 gency”;

5 (B) by amending clause (viii) to read as
6 follows:

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

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

21 (D) by redesignating clause (xii) as clause
22 (xiii); and

23 (E) by inserting after clause (xi) the fol-
24 lowing:

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

12 (2) by redesignating subparagraphs (D)
13 through (H) as subparagraphs (E) through (I), re-
14 spectively; and

15 (3) by inserting after subparagraph (C) the fol-
16 lowing:

17 “(D) an assurance that the entity will re-
18 quire relevant staff to complete relevant pre-
19 paredness and response trainings, including
20 trainings related to efficient and effective oper-
21 ation during an incident or event within an In-
22 cident Command System;”.

23 (b) APPLICABILITY.—The amendments made by sub-
24 section (a) shall not apply with respect to any cooperative

1 agreement entered into prior to the date of enactment of
2 this Act.

3 **SEC. 112. SUPPORTING ACCESS TO MENTAL HEALTH AND**
4 **SUBSTANCE USE DISORDER SERVICES DUR-**
5 **ING PUBLIC HEALTH EMERGENCIES.**

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

8 (1) by redesignating paragraphs (24) and (25)
9 as paragraphs (25) and (26), respectively; and

10 (2) by inserting after paragraph (23) the fol-
11 lowing:

12 “(24) support the continued access to, or avail-
13 ability of, mental health and substance use disorder
14 services during, or in response to, a public health
15 emergency declared under section 319, including in
16 consultation with, as appropriate, the Assistant Sec-
17 retary for Preparedness and Response, the Director
18 of the Centers for Disease Control and Prevention,
19 and the heads of other relevant agencies, in pre-
20 paring for, and responding to, a public health emer-
21 gency;”.

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

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

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

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

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

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

16 (1) by redesignating paragraphs (4) through
17 (7) as paragraphs (5) through (8), respectively;

18 (2) by inserting after paragraph (3) the fol-
19 lowing:

20 “(4) a description of the Administration’s ac-
21 tivities to support the continued provision of mental
22 health and substance use disorder services, as appli-
23 cable, in response to public health emergencies de-
24 clared pursuant to section 319;” and

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

1 (A) by redesignating subparagraphs (D)
2 and (E) as subparagraphs (E) and (F), respec-
3 tively; and

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

6 “(D) relevant preparedness and response
7 activities;”.

8 (d) **ADVISORY COUNCILS.**—Not later than 1 year
9 after the date of enactment of this Act, the Assistant Sec-
10 retary for Mental Health and Substance Use shall issue
11 a report to the Committee on Health, Education, Labor,
12 and Pensions and the Committee on Appropriations of the
13 Senate and the Committee on Energy and Commerce and
14 the Committee on Appropriations of the House of Rep-
15 resentatives, reflecting the feedback of the advisory coun-
16 cils for the Center for Substance Abuse Treatment, the
17 Center for Substance Abuse Prevention, and the Center
18 for Mental Health Services, pursuant to section 502 of
19 the Public Health Service Act (42 U.S.C. 290aa–1), with
20 recommendations to improve the continued provision of
21 mental health and substance use disorder services during
22 a public health emergency declared under section 319 of
23 such Act (42 U.S.C. 247d), and the provision of such serv-
24 ices as part of the public health and medical response to
25 such an emergency, consistent with title XXVIII of such

1 Act (42 U.S.C. 300hh et seq.), including related to the
2 capacity of the mental health and substance use disorder
3 workforce and flexibilities provided to awardees of mental
4 health and substance use disorder programs.

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

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

1 health emergency declared under section 319 of the
2 Public Health Service Act (42 U.S.C. 247d) with re-
3 spect to COVID–19;

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

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

18 **SEC. 113. TRAUMA CARE REAUTHORIZATION.**

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

21 (1) in subsection (a)—

22 (A) in paragraph (3)—

23 (i) by inserting “analyze,” after “com-
24 pile,”; and

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

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

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

6 (D) by redesignating paragraph (6) as
7 paragraph (5);

8 (2) by redesignating subsection (b) as sub-
9 section (c); and

10 (3) by inserting after subsection (a) the fol-
11 lowing:

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

22 “(1) developing, issuing, and updating guid-
23 ance, as appropriate, to support the coordinated
24 medical triage and evacuation to appropriate medical

1 institutions based on patient medical need, taking
2 into account regionalized systems of care;

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

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

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

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

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

24 “(a) IN GENERAL.—The Secretary shall award
25 grants to eligible entities for the purpose of carrying out

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

13 “(b) ELIGIBLE ENTITIES.—

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

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

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

24 “(d) REPORTS.—An entity that receives a grant
25 under this section shall submit to the Secretary such re-

1 ports as the Secretary may require to inform administra-
2 tion of the program under this section.”.

3 (c) PILOT GRANTS FOR TRAUMA CENTERS.—Section
4 1204 of the Public Health Service Act (42 U.S.C. 300d–
5 6) is amended—

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

9 (2) in subsection (a)—

10 (A) by striking “not fewer than 4” and in-
11 sserting “10”;

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

15 (C) by striking “emergency care” and in-
16 sserting “emergency medical”; and

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

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

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

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

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

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

9 (4) in subsection (c)—

10 (A) in the matter preceding paragraph
11 (1)—

12 (i) by striking “that proposes a pilot
13 project”;

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

21 (B) in paragraph (1) —

22 (i) by striking “coordinates” and in-
23 serting “Strengthening coordination and
24 communication”; and

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

11 (C) in paragraph (2)—

12 (i) by striking “includes” and insert-
13 ing “Providing”;

14 (ii) by inserting “support patient
15 movement to” after “region to”; and

16 (iii) by striking the semicolon and in-
17 serting a period;

18 (D) in paragraph (3)—

19 (i) by striking “allows for” and insert-
20 ing “Improving”; and

21 (ii) by striking “; and” and inserting
22 a period;

23 (E) in paragraph (4), by striking “includes
24 a consistent” and inserting “Supporting a con-
25 sistent”; and

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

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

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

11 (5) in subsection (d)(2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),
14 by striking “the proposed” and inserting
15 “the applicable emergency medical and
16 trauma system”;

17 (ii) in clause (i), by inserting “or
18 Tribal entity” after “equivalent State of-
19 fice”; and

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

22 (B) by redesignating subparagraph (B) as
23 subparagraph (C); and

24 (C) by inserting after subparagraph (A)
25 the following:

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

8 (6) in subsection (e)—

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

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

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

20 (7) in subsection (f), by striking “population in
21 a medically underserved area” and inserting “medi-
22 cally underserved population”;

23 (8) in subsection (g)—

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

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

5 (C) by striking paragraph (4);

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

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

10 (F) in paragraph (5), as so redesignated,
11 by striking the period and inserting “; and”;
12 and

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

14 “(6) any evidence-based or evidence-informed
15 strategies developed or utilized pursuant to sub-
16 section (c)(5).”; and

17 (9) by amending subsection (h) to read as fol-
18 lows:

19 “(h) DISSEMINATION OF FINDINGS.—Not later than
20 1 year after the completion of the final project under sub-
21 section (a), the Secretary shall submit to the Committee
22 on Health, Education, Labor, and Pensions of the Senate
23 and the Committee on Energy and Commerce of the
24 House of Representatives a report describing the informa-
25 tion contained in each report submitted pursuant to sub-

1 section (g) and any additional actions planned by the Sec-
2 retary related to regionalized emergency care and trauma
3 systems.”.

4 (d) PROGRAM FUNDING.—Section 1232(a) of the
5 Public Health Service Act (42 U.S.C. 300d–32(a)) is
6 amended by striking “2010 through 2014” and inserting
7 “2023 through 2027”.

8 **SEC. 114. ASSESSMENT OF CONTAINMENT AND MITIGATION**
9 **OF INFECTIOUS DISEASES.**

10 (a) GAO STUDY.—The Comptroller General of the
11 United States shall conduct a study that reviews a geo-
12 graphically diverse sample of States and territories that,
13 in response to the COVID–19 pandemic, implemented pre-
14 paredness and response plans that included isolation and
15 quarantine recommendations or requirements. Such study
16 shall include—

17 (1) a review of such State and territorial pre-
18 paredness and response plans in place during the
19 COVID–19 pandemic, an assessment of the extent
20 to which such plans facilitated or presented chal-
21 lenges to State and territorial responses to such
22 public health emergency, including response activi-
23 ties relating to isolation and quarantine to prevent
24 the spread of COVID–19; and

1 with regard to addressing unique public health challenges
2 in such States and territories associated with such public
3 health emergency.

4 **TITLE II—IMPROVING PUBLIC**
5 **HEALTH PREPAREDNESS AND**
6 **RESPONSE CAPACITY**

7 **Subtitle A—Addressing Disparities**
8 **and Improving Public Health**
9 **Emergency Responses**

10 **SEC. 201. ADDRESSING SOCIAL DETERMINANTS OF HEALTH**
11 **AND IMPROVING HEALTH OUTCOMES.**

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

14 (1) by inserting after section 317U the fol-
15 lowing:

16 **“SEC. 317V. ADDRESSING SOCIAL DETERMINANTS OF**
17 **HEALTH AND IMPROVING HEALTH OUT-**
18 **COMES.**

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

1 ties to address social determinants of health in commu-
2 nities.

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

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

14 “(B) be a consortia of entities described in sub-
15 paragraph (A) or a public-private partnership, in-
16 cluding a community partnership;

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

20 “(3) in the case of an entity other than a com-
21 munity-based organization, demonstrate a history of
22 successfully working with an established community-
23 based organization to address health disparities;

24 “(4) submit a plan to conduct activities de-
25 scribed in subsection (a) based on a community

1 needs assessment that takes into account community
2 input; and

3 “(5) demonstrate the capacity to effectively im-
4 plement evidence-based or evidence-informed strate-
5 gies to address health disparities among underserved
6 populations, which may include rural, racial, and
7 ethnic minority populations and people with disabil-
8 ities, in a timely manner.

9 “(c) USE OF FUNDS.—An entity described in sub-
10 section (b) shall use funds received under subsection (a),
11 in consultation with State, local, and Tribal health depart-
12 ments, community-based organizations, entities serving
13 medically underserved communities, and other entities, as
14 applicable, with experience addressing social determinants
15 of health or reducing health disparities, as applicable, for
16 one or more of the following purposes:

17 “(1) Supporting the implementation, evaluation,
18 and dissemination of strategies, including culturally-
19 appropriate strategies, to address social deter-
20 minants of health, based on the identified needs of
21 the community that is the subject of the assessment
22 submitted under subsection (b)(4), through evidence-
23 informed or evidence-based programs and through
24 the support and use of public health and health care

1 professionals to address such social determinants of
2 health.

3 “(2) Establishing, maintaining, or improving, in
4 consultation with State, local, or Tribal health de-
5 partments, technology platforms or networks to sup-
6 port, in a manner that is consistent with applicable
7 Federal and State privacy law—

8 “(A) coordination among appropriate enti-
9 ties;

10 “(B) information sharing on health and re-
11 lated social services;

12 “(C) technical assistance and related sup-
13 port for entities participating in the platforms
14 or networks; and

15 “(D) as applicable and appropriate, activi-
16 ties to improve data collection for public health
17 purposes and activities to improve coordination.

18 “(3) Implementing best practices for improving
19 health outcomes and reducing disease among under-
20 served populations, including rural or racial and eth-
21 nic minority populations.

22 “(4) Supporting consideration of social deter-
23 minants of health in preparing for, and responding
24 to, public health emergencies, through outreach,
25 education, research, and other relevant activities.

1 “(d) BEST PRACTICES AND TECHNICAL ASSIST-
2 ANCE.—The Secretary, in consultation with the Director
3 of the Office of Minority Health, the National Coordinator
4 for Health Information Technology, and the Adminis-
5 trator of the Administration for Community Living, may
6 award grants, contracts, and cooperative agreements to
7 public or nonprofit private entities, including minority
8 serving institutions (defined, for purposes of this sub-
9 section, as institutions and programs described in section
10 326(e)(1) of the Higher Education Act of 1965 and insti-
11 tutions described in section 371(a) of such Act of 1965),
12 to—

13 “(1) identify or facilitate the development of
14 best practices to support improved health outcomes
15 and reduce health disparities by addressing social
16 determinants of health;

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

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

22 “(4) leverage, establish, or operate regional cen-
23 ters to develop, evaluate, and disseminate effective
24 strategies on the utilization of preventive health care
25 services to address social determinants of health, in-

1 including supporting research and training related to
2 such strategies.

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

7 “(f) REPORT.—Not later than September 30, 2026,
8 the Secretary shall submit to the Committee on Health,
9 Education, Labor, and Pensions of the Senate and the
10 Committee on Energy and Commerce of the House of
11 Representatives a report that includes information on ac-
12 tivities funded under this section. Such report shall in-
13 clude a description of—

14 “(1) changes in the capacity of public health
15 entities to address social determinants of health in
16 communities, including any applicable platforms or
17 networks developed or utilized to coordinate health
18 and related social services and any changes in work-
19 force capacity or capabilities;

20 “(2) improvements in health outcomes and in
21 reducing health disparities in medically underserved
22 communities;

23 “(3) activities conducted to support consider-
24 ation of social determinants of health in preparing
25 for, and responding to, public health emergencies,

1 through outreach, education, and other relevant ac-
2 tivities;

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

5 “(5) activities supported under subsection (e);
6 and

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

9 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
10 carry out this section, there are authorized to be appro-
11 priated \$70,000,000 for each of fiscal years 2023 through
12 2027.”; and

13 (2) by striking section 330D (42 U.S.C. 254c-
14 4).

15 (b) GAO STUDY AND REPORT.—Not later than 4
16 years after the date of enactment of this Act, the Comp-
17 troller General of the United States shall submit to the
18 Committee on Health, Education, Labor, and Pensions of
19 the Senate and the Energy and Committee on Energy and
20 Commerce of the House of Representatives a report on
21 the program authorized under section 317V of the Public
22 Health Service Act, as added by subsection (a), including
23 a review of the outcomes and effectiveness of the program
24 and coordination with other programs in the Department

1 of Health and Human Services with similar goals to en-
2 sure that there was no unnecessary duplication of efforts.

3 **SEC. 202. NATIONAL ACADEMIES OF SCIENCES, ENGINEER-**
4 **ING, AND MEDICINE REPORT.**

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

14 (b) REPORT.—Pursuant to the contract under sub-
15 section (a), the National Academies shall, not later than
16 3 years after the date of enactment of this Act, issue a
17 report informed by the study conducted under such sub-
18 section that includes—

19 (1) consideration of previous recommendations
20 made by the National Academies related to health
21 disparities, including in the report titled “Unequal
22 Treatment: Confronting Racial and Ethnic Dispari-
23 ties in Healthcare”;

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

4 (3) an assessment of ongoing research and
5 strategies to reduce health disparities and improve
6 health outcomes, including effective service delivery
7 models.

8 (c) CLARIFICATION.—In completing the requirements
9 of the contract under this section, the National Academies
10 may leverage relevant ongoing work of the National Acad-
11 emies, including ongoing work related to the impact of
12 Federal policies on health disparities.

13 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
14 authorized to be appropriated \$2,000,000 for fiscal year
15 2023 to carry out this section.

16 **Subtitle B—Improving Public** 17 **Health Data**

18 **SEC. 211. MODERNIZING BIOSURVEILLANCE CAPABILITIES** 19 **AND INFECTIOUS DISEASE DATA COLLEC-** 20 **TION.**

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

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

25 (2) in subsection (c)—

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

3 (B) in paragraph (3)(B), by inserting “,
4 and make recommendations to improve the
5 quality of data collected pursuant to subpara-
6 graph (A) to ensure complete, accurate, and
7 timely sharing of such data, as appropriate,
8 across such elements as described in subpara-
9 graph (A)” after “under subparagraph (A)”;

10 (C) in paragraph (5)—

11 (i) in subparagraph (A)—

12 (I) in the matter preceding clause
13 (i), by striking “and operating” and
14 inserting “, operating, and updating,
15 as appropriate,”;

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

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

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

22 “(vi) in collaboration with State, local,
23 and Tribal public health officials, integrate
24 and update applicable existing public
25 health data systems and networks of the

1 Department of Health and Human Serv-
2 ices to reflect technological advancements,
3 consistent with section 2823, as applica-
4 ble.”; and

5 (ii) in subparagraph (B)—

6 (I) in clause (i), by inserting
7 “and 180 days after the date of enact-
8 ment of the PREVENT Pandemics
9 Act,” after “Innovation Act of
10 2019,”;

11 (II) in clause (ii), by inserting
12 “experts in privacy and data secu-
13 rity;” after “forecasting;”; and

14 (III) in clause (iii)—

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

17 (bb) in subclause (VI), by
18 striking the period and inserting
19 a semicolon; and

20 (cc) by adding at the end
21 the following:

22 “(VII) strategies to integrate lab-
23 oratory and public health data sys-
24 tems and capabilities to support rapid
25 and accurate reporting of laboratory

1 test results and associated relevant
2 data;

3 “(VIII) strategies to improve the
4 collection and reporting of relevant,
5 aggregated, deidentified demographic
6 data to inform responses to public
7 health emergencies, including identi-
8 fication of at-risk populations and to
9 address potential health disparities;
10 and

11 “(IX) strategies to improve the
12 electronic exchange of health informa-
13 tion between State and local health
14 departments and health care providers
15 and facilities to improve public health
16 surveillance.”; and

17 (D) in paragraph (6)(A)—

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

21 (ii) in clause (iii)—

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

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

1 “(V) improve coordination and
2 collaboration, as appropriate, with
3 other Federal departments; and

4 “(VI) implement applicable les-
5 sons learned from recent public health
6 emergencies to address gaps in situa-
7 tional awareness and biosurveillance
8 capabilities;”;

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

11 (iv) in clause (v), by striking the pe-
12 riod and inserting “, including a descrip-
13 tion of how such steps will further the
14 goals of the network, consistent with para-
15 graph (1); and”;

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

17 “(vi) identifies and demonstrates
18 measurable steps the Secretary will take to
19 further develop and integrate infectious
20 disease detection, support rapid and accu-
21 rate reporting of laboratory test results
22 during a public health emergency, and im-
23 prove coordination and collaboration with
24 State, local, and Tribal public health offi-
25 cials, clinical laboratories, and other enti-

1 ties with expertise in public health surveil-
2 lance.”;

3 (3) in subsection (d)—

4 (A) in paragraph (1), by inserting “, act-
5 ing through the Director of the Centers for Dis-
6 ease Control and Prevention and in coordina-
7 tion with the heads of other appropriate agen-
8 cies and offices within the Department of
9 Health and Human Services,” after “the Sec-
10 retary”;

11 (B) in paragraph (2)(C), by inserting “,
12 including any public-private partnerships or
13 other partnerships entered into to improve such
14 capacity” before the semicolon; and

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

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

21 (4) by amending subsection (i) to read as fol-
22 lows:

23 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated—

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

3 “(2) to carry out subsections (b), (c), and (d),
4 \$136,800,000 for each of fiscal years 2022 and
5 2023.”; and

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

8 **SEC. 212. GENOMIC SEQUENCING, ANALYTICS, AND PUBLIC**
9 **HEALTH SURVEILLANCE OF PATHOGENS.**

10 (a) GUIDANCE SUPPORTING GENOMIC SEQUENCING
11 OF PATHOGENS COLLABORATION.—The Secretary of
12 Health and Human Services (referred to in this section
13 as the “Secretary”), in consultation with the heads of
14 other Federal departments or agencies, as appropriate,
15 shall issue guidance to support collaboration relating to
16 genomic sequencing of pathogens, including the use of new
17 and innovative approaches and technology for the detec-
18 tion, characterization, and sequencing of pathogens, to im-
19 prove public health surveillance and preparedness and re-
20 sponse activities, consistent with section 2824 of the Pub-
21 lic Health Service Act, as added by subsection (b). Such
22 guidance shall address the secure sharing, for public
23 health surveillance purposes, of specimens of such patho-
24 gens, between appropriate entities and public health au-
25 thorities, consistent with the regulations promulgated

1 under section 264(c) of the Health Insurance Portability
2 and Accountability Act of 1996 (42 U.S.C. 1320d–2 note),
3 as applicable, and in a manner that protects personal pri-
4 vacy to the extent required by applicable privacy law, at
5 a minimum, and the appropriate use of sequence data de-
6 rived from such specimens.

7 (b) GENOMIC SEQUENCING PROGRAM.—Title
8 XXVIII of the Public Health Service Act (42 U.S.C.
9 300hh et seq.) is amended by adding at the end the fol-
10 lowing

11 **“SEC. 2824. GENOMIC SEQUENCING, ANALYTICS, AND PUB-**
12 **LIC HEALTH SURVEILLANCE OF PATHOGENS**
13 **PROGRAM.**

14 “(a) GENOMIC SEQUENCING, ANALYTICS, AND PUB-
15 LIC HEALTH SURVEILLANCE OF PATHOGENS PRO-
16 GRAM.—The Secretary, acting through the Director of the
17 Centers for Disease Control and Prevention and in con-
18 sultation with the Director of the National Institutes of
19 Health and heads of other departments and agencies, as
20 appropriate, shall strengthen and expand activities related
21 to genomic sequencing of pathogens, including new and
22 innovative approaches and technology for the detection,
23 characterization, and sequencing of pathogens, analytics,
24 and public health surveillance, including—

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

4 “(A) identify and respond to emerging in-
5 fectious disease threats; and

6 “(B) identify the potential use of genomic
7 sequencing technologies, advanced computing,
8 and other advanced technology to inform sur-
9 veillance activities and incorporate the use of
10 such technologies, as appropriate, into related
11 activities;

12 “(2) providing technical assistance and guid-
13 ance to State, Tribal, local, and territorial public
14 health departments to increase the capacity of such
15 departments to perform genomic sequencing of
16 pathogens, including recipients of funding under sec-
17 tion 2821;

18 “(3) carrying out activities to enhance the capa-
19 bilities of the public health workforce with respect to
20 pathogen genomics, epidemiology, and
21 bioinformatics, including through training; and

22 “(4) continuing and expanding activities, as ap-
23 plicable, with public and private entities, including
24 relevant departments and agencies, laboratories, aca-
25 demic institutions, and industry.

1 “(b) PARTNERSHIPS.—For the purposes of carrying
2 out the activities described in subsection (a), the Sec-
3 retary, acting through the Director of the Centers for Dis-
4 ease Control and Prevention, may award grants, contracts,
5 or cooperative agreements to entities, including academic
6 and other laboratories, with expertise in genomic sequenc-
7 ing for public health purposes, including new and innova-
8 tive approaches to, and related technology for, the detec-
9 tion, characterization, and sequencing of pathogens.

10 “(c) CENTERS OF EXCELLENCE.—

11 “(1) IN GENERAL.—The Secretary shall, as ap-
12 propriate, award grants, contracts, or cooperative
13 agreements to public health agencies for the estab-
14 lishment or operation of centers of excellence to pro-
15 mote innovation in pathogen genomics and molecular
16 epidemiology to improve the control of and response
17 to pathogens that may cause a public health emer-
18 gency. Such centers shall, as appropriate—

19 “(A) identify and evaluate the use of
20 genomics, or other related technologies that
21 may advance public health preparedness and re-
22 sponse;

23 “(B) improve the identification, develop-
24 ment, and use of tools for integrating and ana-
25 lyzing genomic and epidemiologic data;

1 “(C) assist with genomic surveillance of,
2 and response to, infectious diseases, including
3 analysis of pathogen genomic data;

4 “(D) conduct applied research to improve
5 public health surveillance of, and response to,
6 infectious diseases through innovation in patho-
7 gen genomics and molecular epidemiology; and

8 “(E) develop and provide training mate-
9 rials for experts in the fields of genomics,
10 microbiology, bioinformatics, epidemiology, and
11 other fields, as appropriate.

12 “(2) REQUIREMENTS.—To be eligible for an
13 award under paragraph (1), an entity shall submit
14 to the Secretary an application containing such in-
15 formation as the Secretary may require, including a
16 description of how the entity will partner, as applica-
17 ble, with academic institutions or a consortium of
18 academic partners that have relevant expertise, such
19 as microbial genomics, molecular epidemiology, or
20 the application of bioinformatics or statistics.

21 “(d) AUTHORIZATION.—For purposes of carrying out
22 this section, there are authorized to be appropriated
23 \$175,000,000 for each of fiscal years 2023 through
24 2027.”.

1 **SEC. 213. SUPPORTING PUBLIC HEALTH DATA AVAIL-**
2 **ABILITY AND ACCESS.**

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

6 (1) by striking “In carrying out” and inserting
7 the following:

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

9 (2) by striking “shall, as appropriate and” and
10 inserting “shall, not later than 2 years after the date
11 of enactment of the PREVENT Pandemics Act,”;
12 and

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

14 “(B) SELECTION OF DATA AND TECH-
15 NOLOGY STANDARDS.—The standards des-
16 igned as described in subparagraph (A) may
17 include standards to improve—

18 “(i) the exchange of electronic health
19 information for—

20 “(I) electronic case reporting;

21 “(II) syndromic surveillance;

22 “(III) reporting of vital statistics;

23 and

24 “(IV) reporting test orders and
25 results electronically, including from
26 laboratories;

1 “(ii) automated electronic reporting to
2 relevant public health data systems of the
3 Centers for Disease Control and Preven-
4 tion; and

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

7 “(C) NO DUPLICATIVE EFFORTS.—

8 “(i) IN GENERAL.—In carrying out
9 the requirements of this paragraph, the
10 Secretary, in consultation with the Office
11 of the National Coordinator for Health In-
12 formation Technology, may use input gath-
13 ered (including input and recommendations
14 gathered from the Health Information
15 Technology Advisory Committee), and ma-
16 terials developed, prior to the date of en-
17 actment of the PREVENT Pandemics Act.

18 “(ii) DESIGNATION OF STANDARDS.—
19 Consistent with sections 13111 and 13112
20 of the HITECH Act, the data and tech-
21 nology standards designated pursuant to
22 this paragraph shall align with the stand-
23 ards and implementation specifications
24 previously adopted by the Secretary pursu-
25 ant to section 3004, as applicable.

1 “(D) PRIVACY AND SECURITY.—Nothing
2 in this paragraph shall be construed as modi-
3 fying applicable Federal or State information
4 privacy or security law.”.

5 (b) STUDY ON LABORATORY INFORMATION STAND-
6 ARDS.—

7 (1) IN GENERAL.—Not later than 1 year after
8 the date of enactment of this Act, the Office of the
9 National Coordinator for Health Information Tech-
10 nology shall conduct a study to review the use of
11 standards for electronic ordering and reporting of
12 laboratory test results.

13 (2) AREAS OF CONCENTRATION.—In conducting
14 the study under paragraph (1), the Office of the Na-
15 tional Coordinator for Health Information Tech-
16 nology shall—

17 (A) determine the extent to which clinical
18 laboratories are using standards for electronic
19 ordering and reporting of laboratory test re-
20 sults;

21 (B) assess trends in laboratory compliance
22 with standards for ordering and reporting lab-
23 oratory test results and the effect of such
24 trends on the interoperability of laboratory data
25 with public health data systems;

1 (C) identify challenges related to collection
2 and reporting of demographic and other data
3 elements with respect to laboratory test results;

4 (D) identify any challenges associated with
5 using or complying with standards and report-
6 ing laboratory test results with data elements
7 identified in standards for electronic ordering
8 and reporting of such results; and

9 (E) review other relevant areas determined
10 appropriate by the Office of the National Coor-
11 dinator for Health Information Technology.

12 (3) REPORT.—Not later than 2 years after the
13 date of enactment of this Act, the Office of the Na-
14 tional Coordinator for Health Information Tech-
15 nology shall submit to the Committee on Health,
16 Education, Labor, and Pensions of the Senate and
17 the Committee on Energy and Commerce of the
18 House of Representatives a report concerning the
19 findings of the study conducted under paragraph
20 (1).

21 (c) SUPPORTING INFORMATION SHARING THROUGH
22 DATA USE AGREEMENTS.—

23 (1) INTERAGENCY DATA USE AGREEMENTS
24 WITHIN THE DEPARTMENT OF HEALTH AND HUMAN
25 SERVICES FOR PUBLIC HEALTH EMERGENCIES.—

1 (A) IN GENERAL.—The Secretary of
2 Health and Human Services (referred to in this
3 subsection as the “Secretary”) shall, as appro-
4 priate, facilitate the development of, or updates
5 to, memoranda of understanding, data use
6 agreements, or other applicable interagency
7 agreements regarding appropriate access, ex-
8 change, and use of public health data between
9 the Centers for Disease Control and Prevention,
10 the Office of the Assistant Secretary for Pre-
11 paredness and Response, other relevant agen-
12 cies or offices within the Department of Health
13 and Human Services, and other relevant Fed-
14 eral agencies, in order to prepare for, identify,
15 monitor, and respond to declared or potential
16 public health emergencies.

17 (B) REQUIREMENTS.—In carrying out ac-
18 tivities pursuant to subparagraph (A), the Sec-
19 retary shall—

20 (i) ensure that the agreements and
21 memoranda of understanding described in
22 such subparagraph—

23 (I) address the methods of grant-
24 ing access to data held by one agency
25 or office with another to support the

1 respective missions of such agencies
2 or offices;

3 (II) consider minimum necessary
4 principles of data sharing for appro-
5 priate use;

6 (III) include appropriate privacy
7 and cybersecurity protections; and

8 (IV) are subject to regular up-
9 dates, as appropriate;

10 (ii) collaborate with the Centers for
11 Disease Control and Prevention, the Office
12 of the Assistant Secretary for Prepared-
13 ness and Response, the Office of the Chief
14 Information Officer, and, as appropriate,
15 the Office of the National Coordinator for
16 Health Information Technology, and other
17 entities within the Department of Health
18 and Human Services; and

19 (iii) consider the terms and conditions
20 of any existing data use agreements with
21 other public or private entities and any
22 need for updates to such existing agree-
23 ments, consistent with paragraph (2).

24 (2) DATA USE AGREEMENTS WITH EXTERNAL
25 ENTITIES.—The Secretary, acting through the Di-

1 rector of the Centers for Disease Control and Pre-
2 vention and the Assistant Secretary for Prepared-
3 ness and Response, may update memoranda of un-
4 derstanding, data use agreements, or other applica-
5 ble agreements and contracts to improve appropriate
6 access, exchange, and use of public health data be-
7 tween the Centers for Disease Control and Preven-
8 tion and the Office of the Assistant Secretary for
9 Preparedness and Response and external entities, in-
10 cluding State, Tribal, and territorial health depart-
11 ments, laboratories, hospitals and other health care
12 providers, electronic health records vendors, and
13 other entities, as applicable and appropriate, in
14 order to prepare for, identify, monitor, and respond
15 to declared or potential public health emergencies.

16 (3) REPORT.—Not later than 90 days after the
17 date of enactment of this Act, the Secretary shall re-
18 port to the Committee on Health, Education, Labor,
19 and Pensions of the Senate and the Committee on
20 Energy and Commerce of the House of Representa-
21 tives on the status of the agreements under this sub-
22 section.

23 (d) IMPROVING INFORMATION SHARING AND AVAIL-
24 ABILITY OF PUBLIC HEALTH DATA.—Part A of title III

1 of the Public Health Service Act (42 U.S.C. 241 et seq.)
2 is amended by adding at the end the following:

3 **“SEC. 310B. IMPROVING INFORMATION SHARING AND**
4 **AVAILABILITY OF PUBLIC HEALTH DATA.**

5 “(a) IN GENERAL.—The Secretary may, in consulta-
6 tion with State, local, and Tribal public health officials,
7 carry out activities to improve the availability of appro-
8 priate and applicable public health data related to commu-
9 nicable diseases, and information sharing between, the Di-
10 rector of the Centers for Disease Control and Prevention,
11 the Assistant Secretary for Preparedness and Response,
12 and such State, local, and Tribal public health officials,
13 which may include such data from—

14 “(1) health care providers and facilities;

15 “(2) public health and clinical laboratories;

16 “(3) health information exchanges and health
17 information networks; and

18 “(4) State, local, and Tribal health depart-
19 ments.

20 “(b) CONTENT, FORM, AND MANNER.—The Sec-
21 retary shall, consistent with the requirements of this sec-
22 tion, work with such officials and relevant stakeholders to
23 provide information on the content, form, and manner in
24 which such data may most effectively support the ability
25 of State, local, and Tribal health departments to respond

1 to such communicable diseases, including related to the
2 collection and reporting of demographic and other relevant
3 data elements. Such form and manner requirements shall
4 align with the standards and implementation specifica-
5 tions adopted by the Secretary under section 3004, as ap-
6 plicable.

7 “(c) DECREASED BURDEN.—In facilitating the co-
8 ordination of efforts under subsection (a), the Secretary
9 shall make reasonable efforts to limit reported public
10 health data to the minimum necessary information needed
11 to accomplish the intended public health surveillance pur-
12 pose.

13 “(d) EXEMPTION OF CERTAIN PUBLIC HEALTH
14 DATA FROM DISCLOSURE.—The Secretary, acting
15 through the Director of the Centers for Disease Control
16 and Prevention, may exempt from disclosure under section
17 552(b)(3) of title 5, United States Code, public health
18 data that are gathered under this section if—

19 “(1) an individual is identified through such
20 data; or

21 “(2) there is at least a very small risk, as deter-
22 mined by current scientific practices or statistical
23 methods, that some combination of the information,
24 the request, and other available data sources or the

1 application of technology could be used to deduce
2 the identity of an individual.”.

3 (e) IMPROVING PUBLIC HEALTH DATA COLLEC-
4 TION.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services (referred to in this subsection as
7 the “Secretary”) shall award grants, contracts, or
8 cooperative agreements to eligible entities for pur-
9 poses of identifying, developing, or disseminating
10 best practices in the collection of electronic health
11 information and the use of designated data stand-
12 ards and implementation specifications to improve
13 the quality and completeness of data, including de-
14 mographic data, collected, accessed, or used for pub-
15 lic health purposes and to address health disparities
16 and related health outcomes.

17 (2) ELIGIBLE ENTITIES.—To be eligible to re-
18 ceive an award under this subsection an entity
19 shall—

20 (A) be a health care provider, academic
21 medical center, community-based organization,
22 State, local governmental entity, Indian Tribe
23 or Tribal organization (as such terms are de-
24 fined in section 4 of the Indian Self Determina-
25 tion and Education Assistance Act (25 U.S.C.

1 5304)), urban Indian organization (as defined
2 in section 4 of the Indian Health Care Improve-
3 ment Act (25 U.S.C. 1603)), or other appro-
4 priate public or private nonprofit entity, or a
5 consortia of any such entities; and

6 (B) submit an application to the Secretary
7 at such time, in such manner, and containing
8 such information as the Secretary may require.

9 (3) **ACTIVITIES.**—Entities receiving awards
10 under this subsection shall use such award to de-
11 velop and test best practices for training health care
12 providers to use standards and implementation spec-
13 ifications that assist in the capture, access, ex-
14 change, and use of electronic health information, in-
15 cluding demographic information, disability status,
16 veteran status, housing status, functional status,
17 and other data elements. Such activities shall in-
18 clude, at a minimum—

19 (A) improving, understanding, and using
20 data standards and implementation specifica-
21 tions;

22 (B) developing or identifying methods to
23 improve communication with patients in a
24 culturally- and linguistically-appropriate man-

1 ner, including to better capture information re-
2 lated to demographics of such individuals;

3 (C) developing methods for accurately cat-
4 egorizing and recording patient responses using
5 available data standards;

6 (D) educating providers regarding the util-
7 ity of such information for public health pur-
8 poses and the importance of accurate collection
9 and recording of such data; and

10 (E) other activities, as the Secretary deter-
11 mines appropriate.

12 (4) REPORTING.—

13 (A) REPORTING BY AWARD RECIPIENTS.—
14 Each recipient of an award under this sub-
15 section shall submit to the Secretary a report
16 on the results of best practices identified, devel-
17 oped, or disseminated through such award.

18 (B) REPORT TO CONGRESS.—Not later
19 than 1 year after the completion of the program
20 under this subsection, the Secretary shall sub-
21 mit a report to Congress on the success of best
22 practices developed under such program, oppor-
23 tunities for further dissemination of such best
24 practices, and recommendations for improving
25 the capture, access, exchange, and use of infor-

1 mation to improve public health and reduce
2 health disparities.

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

7 (6) AUTHORIZATION OF APPROPRIATIONS.—
8 There are authorized to be appropriated
9 \$10,000,000 for each of fiscal years 2023 through
10 2025 to carry out this subsection.

11 **SEC. 214. EPIDEMIC FORECASTING AND OUTBREAK ANA-**
12 **LYTICS.**

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

16 **“SEC. 2825. EPIDEMIC FORECASTING AND OUTBREAK ANA-**
17 **LYTICS.**

18 “(a) IN GENERAL.—The Secretary, acting through
19 the Director of the Centers for Disease Control and Pre-
20 vention, shall continue activities related to the develop-
21 ment of infectious disease outbreak analysis capabilities
22 to enhance the prediction, modeling, and forecasting of po-
23 tential public health emergencies and other infectious dis-
24 ease outbreaks, which may include activities to support
25 preparedness for, and response to, such emergencies and

1 outbreaks. In carrying out this subsection, the Secretary
2 shall identify strategies to include and leverage, as appro-
3 priate, the capabilities to public and private entities, which
4 may include conducting such activities through collabo-
5 rative partnerships with public and private entities, includ-
6 ing academic institutions, and other Federal agencies, con-
7 sistent with section 319D, as applicable.

8 “(b) CONSIDERATIONS.—In carrying out subsection
9 (a), the Secretary, acting through the Director of the Cen-
10 ters for Disease Control and Prevention, may consider
11 public health data and, as appropriate, other data sources
12 related to preparedness for, or response to, public health
13 emergencies and infectious disease outbreaks.

14 “(c) ANNUAL REPORTS.—Not later than 1 year after
15 the date of enactment of this section, and annually there-
16 after for each of the subsequent 4 years, the Secretary
17 shall prepare and submit a report, to the Committee on
18 Health, Education, Labor, and Pensions of the Senate and
19 the Committee on Energy and Commerce of the House
20 of Representatives, regarding an update on progress on
21 activities conducted under this section to develop infec-
22 tious disease outbreak analysis capabilities and any addi-
23 tional information relevant to such efforts.”.

1 **SEC. 215. PUBLIC HEALTH DATA TRANSPARENCY.**

2 (a) REPORT.—Not later than 1 year after the date
3 of enactment of this Act, the Secretary of Health and
4 Human Services shall issue a report assessing practices,
5 objectives, and associated progress and challenges in
6 achieving such objectives, of the Centers of Disease Con-
7 trol and Prevention with respect to the collection and dis-
8 semination of public health data related to a public health
9 emergency declared under section 319 of the Public
10 Health Service Act (42 U.S.C. 247d) or a potential public
11 health emergency.

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

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

1 (2) recommendations to Congress regarding
2 gaps in such practices and objectives described in
3 subsection (a); and

4 (3) considerations regarding the requirements
5 and limitations of data use agreements for such pur-
6 poses, as applicable.

7 **SEC. 216. GAO REPORT ON PUBLIC HEALTH PREPARED-**
8 **NESS, RESPONSE, AND RECOVERY DATA CA-**
9 **PABILITIES.**

10 (a) **STUDY.**—The Comptroller General of the United
11 States (referred to in this section as the “Comptroller
12 General”) shall conduct a study on the efforts of the De-
13 partment of Health and Human Services to ensure that
14 public health preparedness, response, and recovery data
15 capabilities related to pandemic and other biological
16 threats are not unnecessarily duplicative, overlapping, or
17 fragmented. Such study shall include—

18 (1) a comprehensive list of all public health pre-
19 paredness, response, and recovery data collection,
20 such as incidence and prevalence of disease tracking,
21 hospitalizations, critical care capacity, and testing
22 programs, at the Department of Health and Human
23 Services, as identified by the department and its
24 component agencies;

1 (2) an analysis of any duplication, overlap, or
2 fragmentation of the programs identified in para-
3 graph (1);

4 (3) identification of any efforts of the Depart-
5 ment of Health and Human Services to reduce un-
6 necessary duplication and improve coordination, effi-
7 ciency, and effectiveness of such programs and any
8 associated challenges; and

9 (4) a description of the funding and other re-
10 sources dedicated to the operation of each such pro-
11 gram identified in paragraph (1).

12 (b) REPORTING.—

13 (1) IN GENERAL.—Based on the study con-
14 ducted under subsection (a), the Comptroller Gen-
15 eral shall—

16 (A) not later than 6 months after the date
17 of enactment of this Act, provide a briefing to
18 the Committee on Health, Education, Labor,
19 and Pensions of the Senate and the Committee
20 on Energy and Commerce of the House of Rep-
21 resentatives; and

22 (B) not later than 18 months after the
23 date of enactment of this Act, submit to the
24 Committee on Health, Education, Labor, and
25 Pensions of the Senate and the Committee on

1 Energy and Commerce of the House of Rep-
2 resentatives a complete report on such study.

3 (2) RECOMMENDATIONS.—The report under
4 paragraph (1)(B) shall include recommendations, as
5 appropriate, with respect to public health prepared-
6 ness, response, and recovery data programs at the
7 Department of Health and Human Services, to—

8 (A) streamline data collection and reduce
9 fragmentation and address any associated chal-
10 lenges;

11 (B) reduce duplication in such programs;
12 and

13 (C) improve information-sharing across
14 programs.

15 **Subtitle C—Revitalizing the Public**
16 **Health Workforce**

17 **SEC. 221. IMPROVING RECRUITMENT AND RETENTION OF**
18 **THE FRONTLINE PUBLIC HEALTH WORK-**
19 **FORCE.**

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

22 (1) in subsection (a)—

23 (A) by striking “supply of” and inserting
24 “supply of, and encourage recruitment and re-
25 tention of,”; and

1 (B) by striking “Federal,”;

2 (2) in subsection (b)—

3 (A) by amending paragraph (1)(A) to read
4 as follows:

5 “(1)(A)(i) be accepted for enrollment, or be en-
6 rolled, as a student in an accredited institution of
7 higher education or school of public health in the
8 final semester (or equivalent) of a program leading
9 to a certificate or degree, including a master’s or
10 doctoral degree, in public health, epidemiology, lab-
11 oratory sciences, data systems, data science, data
12 analytics, informatics, statistics, or another subject
13 matter related to public health; and

14 “(ii) be employed by, or have accepted employ-
15 ment with, a State, local, or Tribal public health
16 agency, or a related training fellowship at such
17 State, local, or Tribal public health agency, as recog-
18 nized by the Secretary, to commence upon gradua-
19 tion; or”; and

20 (B) in paragraph (1)(B)—

21 (i) in clause (i)—

22 (I) by striking “accredited edu-
23 cational institution in a State or terri-
24 tory” and inserting “accredited insti-

1 tution of higher education or school of
2 public health”; and

3 (II) by striking “a public health
4 or health professions degree or certifi-
5 cate” and inserting “a certificate or
6 degree, including a master’s or doc-
7 toral degree, in public health, epidemi-
8 ology, laboratory sciences, data sys-
9 tems, data science, data analytics,
10 informatics, statistics, or another sub-
11 ject matter related to public health”;
12 and

13 (ii) in clause (ii)—

14 (I) by striking “Federal,”; and

15 (II) by striking “fellowship,” and
16 inserting “fellowship at such State,
17 local, or Tribal public health agency,”;

18 (3) in subsection (c)(2)—

19 (A) by striking “Federal,”; and

20 (B) by striking “equal to the greater of—
21 ” and all that follows through the end of sub-
22 paragraph (B) and inserting “of at least 3 con-
23 secutive years;”;

24 (4) in subsection (d)—

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

3 “(1) IN GENERAL.—A loan repayment provided
4 for an individual under a written contract under the
5 Program shall consist of payment, in accordance
6 with paragraph (2), for the individual toward the
7 outstanding principal and interest on education
8 loans incurred by the individual in the pursuit of the
9 relevant degree or certificate described in subsection
10 (b)(1) in accordance with the terms of the con-
11 tract.”; and

12 (B) in paragraph (2)—

13 (i) by striking “For each year” and
14 inserting the following:

15 “(A) IN GENERAL.—For each year”;

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

18 (iii) by striking “\$105,000” and in-
19 serting “\$150,000”; and

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

22 “(B) CONSIDERATIONS.—The Secretary
23 may take action in making awards under this
24 section to ensure that—

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

5 “(ii) contracts awarded under this
6 section are equitably distributed among—

7 “(I) the geographical regions of
8 the United States;

9 “(II) local, State, and Tribal
10 public health departments; and

11 “(III) such public health depart-
12 ments under subclause (II) serving
13 rural and urban areas.”;

14 (5) in subsection (e), by striking “receiving a
15 degree or certificate from a health professions or
16 other related school” and inserting “with a contract
17 to serve under subsection (c)”;

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

1 (7) by redesignating subsection (g) as sub-
2 section (i);

3 (8) by inserting after subsection (f) the fol-
4 lowing:

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

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

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

11 “(3) Any Federal Direct Stafford Loan, Fed-
12 eral Direct PLUS Loan, Federal Direct Unsub-
13 sidized Stafford Loan, or Federal Direct Consolida-
14 tion Loan (as such terms are used in section 455 of
15 the Higher Education Act of 1965).

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

18 “(5) Any other Federal loan, as the Secretary
19 determines appropriate.

20 “(h) PILOT PROGRAM.—

21 “(1) IN GENERAL.—The Secretary shall, as ap-
22 propriate, establish a pilot program, to be known as
23 the Bio-Preparedness Workforce Pilot Program, to
24 provide for loan repayment for health professionals
25 with expertise in infectious diseases and emergency

1 preparedness and response activities to ensure an
2 adequate supply of such professionals. Such program
3 shall be administered consistent with the require-
4 ments of this section, except that, to be eligible to
5 participate in the pilot program, an individual
6 shall—

7 “(A)(i) be accepted for enrollment, or be
8 enrolled, as a student in an accredited institu-
9 tion of higher education in the final semester
10 (or equivalent) of a program leading to a health
11 professions degree or certificate program rel-
12 evant to such program; or

13 “(ii) have graduated, during the preceding
14 10-year period, from an accredited institution
15 of higher education with a health professions
16 degree or certificate program relevant to such
17 program; and

18 “(B) be employed by, or have accepted em-
19 ployment with—

20 “(i) a Federal health care facility;

21 “(ii) a nonprofit health care facility
22 that is located in a health professional
23 shortage area (as defined in section 332),
24 a frontier health professional shortage area
25 (as defined in section 799B), or a medi-

1 cally underserved community (as defined in
2 section 799B);

3 “(iii) an entity receiving assistance
4 under title XXVI for the provision of clin-
5 ical services;

6 “(iv) a health program, or a facility,
7 operated by an Indian Tribe or Tribal or-
8 ganization (as those terms are defined in
9 section 4 of the Indian Self-Determination
10 and Education Assistance Act) or by an
11 urban Indian organization (as defined in
12 section 4 of the Indian Health Care Im-
13 provement Act); or

14 “(v) another relevant entity deter-
15 mined appropriate by the Secretary, as a
16 health professional with expertise in infec-
17 tious diseases or emergency preparedness
18 and response.

19 “(2) NON-DUPLICATION OF EFFORT.—The Sec-
20 retary shall ensure that the pilot program estab-
21 lished under paragraph (1) does not unnecessarily
22 duplicate the National Health Service Corps Loan
23 Repayment Program, or any other loan repayment
24 program operated by the Department of Health and
25 Human Services.

1 “(3) EVALUATION AND REPORT TO CON-
2 GRESS.—

3 “(A) IN GENERAL.—The Secretary shall
4 evaluate the pilot program at the conclusion of
5 the first cycle of recipients funded by the pilot
6 program.

7 “(B) REPORT.—

8 “(i) IN GENERAL.—The Secretary
9 shall submit to the Committee on Health,
10 Education, Labor, and Pensions of the
11 Senate and the Committee on Energy and
12 Commerce of the House of Representatives
13 a report on the evaluation under subpara-
14 graph (A). The report shall include, at a
15 minimum, outcomes information from the
16 pilot program, including any impact on re-
17 cruitment and retention of health profes-
18 sionals with expertise in infectious diseases
19 and emergency preparedness and response
20 activities.

21 “(ii) RECOMMENDATION.—The report
22 under this subparagraph shall include a
23 recommendation by the Secretary as to
24 whether the pilot program under this sub-
25 section should be extended.”;

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

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

9 (b) GAO STUDY ON PUBLIC HEALTH WORK-
10 FORCE.—Not later than 2 years after the date of enact-
11 ment of this Act, the Comptroller General of the United
12 States shall—

13 (1) conduct an evaluation of what is known
14 about the public health workforce in the United
15 States, which shall address—

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

21 (B) challenges associated with the hiring,
22 recruitment, and retention of the Federal,
23 State, local, Tribal, and territorial public health
24 workforce; and

1 (C) Federal efforts to improve hiring, re-
2 cruitment, and retention of the public health
3 workforce; and

4 (2) submit to the Committee on Health, Edu-
5 cation, Labor, and Pensions of the Senate and the
6 Committee on Energy and Commerce of the House
7 of Representatives a report on such review.

8 **SEC. 222. AWARDS TO SUPPORT COMMUNITY HEALTH**
9 **WORKERS AND COMMUNITY HEALTH.**

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

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

15 (2) by amending subsection (a) to read as fol-
16 lows:

17 “(a) IN GENERAL.—The Secretary, acting through
18 the Director of the Centers for Disease Control and Pre-
19 vention and in coordination with the Administrator of the
20 Health Resources and Services Administration, shall
21 award grants, contracts, or cooperative agreements to eli-
22 gible entities to promote positive health behaviors and out-
23 comes for populations in medically underserved commu-
24 nities by leveraging community health workers, including
25 by addressing ongoing and longer-term community health

1 needs, and by building the capacity of the community
2 health worker workforce. Such grants, contracts, and co-
3 operative agreements shall be awarded in alignment and
4 coordination with existing funding arrangements sup-
5 porting community health workers.”;

6 (3) in subsection (b)—

7 (A) in the matter preceding paragraph

8 (1)—

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

16 (ii) by striking “support community
17 health workers”;

18 (B) by redesignating paragraphs (3)
19 through (5) as paragraphs (4) through (6), re-
20 spectively;

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

23 “(1) recruit, hire, train, and retain community
24 health workers that reflect the needs of the commu-
25 nity;

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

4 “(A) health conditions prevalent in—

5 “(i) medically underserved commu-
6 nities (as defined in section 799B), par-
7 ticularly racial and ethnic minority popu-
8 lations; and

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

17 “(B) addressing social determinants of
18 health and eliminating health disparities, in-
19 cluding by—

20 “(i) promoting awareness of services
21 and resources to increase access to health
22 care, mental health and substance use dis-
23 order services, child services, technology,
24 housing services, educational services, nu-

1 trition services, employment services, and
2 other services; and

3 “(ii) assisting in conducting individual
4 and community needs assessments;

5 “(3) educate community members, including re-
6 garding effective strategies to promote healthy be-
7 haviors;”;

8 (D) in paragraph (4), as so redesignated,
9 by striking “to educate” and inserting “edu-
10 cate”;

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

12 (i) by striking “to identify” and in-
13 serting “identify”;

14 (ii) by striking “healthcare agencies”
15 and inserting “health care agencies”; and

16 (iii) by striking “healthcare services
17 and to eliminate duplicative care; or” and
18 inserting “health care services and to
19 streamline care, including serving as a liai-
20 son between communities and health care
21 agencies; and”; and

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

23 (i) by striking “to educate, guide, and
24 provide” and inserting “support commu-

1 nity health workers in educating, guiding,
2 or providing”; and

3 (ii) by striking “maternal health and
4 prenatal care” and inserting “chronic dis-
5 eases, maternal health, prenatal, and
6 postpartum care in order to improve ma-
7 ternal and infant health outcomes”;

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

14 (5) in subsection (d)—

15 (A) in the matter preceding paragraph (1),
16 by striking “awarding grants” and inserting
17 “making awards”;

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

20 “(1) propose to serve—

21 “(A) areas with populations that have a
22 high rate of chronic disease, infant mortality, or
23 maternal morbidity and mortality;

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

4 “(C) populations residing in health profes-
5 sional shortage areas (as defined in section
6 332(a));

7 “(D) populations residing in maternity
8 care health professional target areas identified
9 under section 332(k); or

10 “(E) rural or traditionally underserved
11 populations, including racial and ethnic minor-
12 ity populations or low-income populations;”;

13 (C) in paragraph (2), by striking “; and”
14 and inserting “, including rural populations and
15 racial and ethnic minority populations;”;

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

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

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

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

4 (6) in subsection (e)—

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

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

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

19 “(f) TECHNICAL ASSISTANCE.—The Secretary may
20 provide to eligible entities that receive awards under sub-
21 section (a) technical assistance with respect to planning,
22 development, and operation of community health worker
23 programs authorized or supported under this section.

24 “(g) DISSEMINATION OF BEST PRACTICES.—Not
25 later than 4 years after the date of enactment of the PRE-

1 VENT Pandemics Act, the Secretary shall, based on ac-
2 tivities carried out under this section and in consultation
3 with relevant stakeholders, identify and disseminate evi-
4 dence-based or evidence-informed practices regarding re-
5 cruitment and retention of community health workers and
6 paraprofessionals to address ongoing public health and
7 community health needs, and to prepare for, and respond
8 to, future public health emergencies.

9 “(h) REPORT TO CONGRESS.—Not later than 4 years
10 after the date of enactment of the PREVENT Pandemics
11 Act, the Secretary shall submit to the Committee on
12 Health, Education, Labor, and Pensions and the Com-
13 mittee on Appropriations of the Senate and the Committee
14 on Energy and Commerce and the Committee on Appro-
15 priations of the House of Representatives a report con-
16 cerning the effectiveness of the program under this section
17 in addressing ongoing public health and community health
18 needs. Such report shall include recommendations regard-
19 ing any improvements to such program, including rec-
20 ommendations for how to improve recruitment, training,
21 and retention of the community health workforce.

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

1 (8) by redesignating subsection (k) as sub-
2 section (j); and

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

4 (A) by striking paragraphs (1), (2), and
5 (4);

6 (B) by redesignating paragraph (3) as
7 paragraph (1);

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

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

16 (ii) by striking “as defined in section
17 1861(aa) of the Social Security Act))” and
18 inserting “(as defined in section
19 1861(aa)(4) of the Social Security Act)”;
20 and

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

22 “(2) INDIAN TRIBE; TRIBAL ORGANIZATION.—
23 The terms ‘Indian Tribe’ and ‘Tribal organization’
24 have the meanings given the terms ‘Indian tribe’ and
25 ‘tribal organization’, respectively, in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act.

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

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

22 **SEC. 223. IMPROVING PUBLIC HEALTH EMERGENCY RE-**
23 **SPONSE CAPACITY.**

24 (a) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC
25 HEALTH EMERGENCY RESPONSES.—Section 319 of the

1 Public Health Service Act (42 U.S.C. 247d) is amended
2 by adding at the end the following:

3 “(g) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC
4 HEALTH EMERGENCY RESPONSES.—

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

14 “(A) address a critical hiring need directly
15 related to responding to a public health emer-
16 gency declared by the Secretary under this sec-
17 tion; or

18 “(B) address a severe shortage of can-
19 didates that impacts the operational capacity of
20 the Department of Health and Human Services
21 to respond in the event of a public health emer-
22 gency declared by the Secretary under this sec-
23 tion.

24 “(2) NUMBER OF APPOINTMENTS.—Each fiscal
25 year in which the Secretary makes a determination

1 of a public health emergency under subsection (a)
2 (not including a renewal), the Secretary may directly
3 appoint not more than—

4 “(A) 400 individuals under paragraph
5 (1)(A); and

6 “(B) 100 individuals under paragraph
7 (1)(B).

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

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

16 “(A) the number of positions filled through
17 such authority;

18 “(B) the types of appointments of such po-
19 sitions;

20 “(C) the titles, occupational series, and
21 grades of such positions;

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

24 “(E) the number of qualified applicants
25 who apply for such positions;

1 “(F) the qualification criteria for such po-
2 sitions; and

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

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

18 “(A) information on each such appoint-
19 ment within such fiscal year;

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

23 “(C) the additional number of personnel, if
24 any, the Secretary anticipates to be necessary
25 to adequately support a response to a public

1 health emergency declared under this section
2 using the authorities described in paragraph (1)
3 within such fiscal year.

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

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

18 (b) GAO REPORT.—Not later than 1 year after the
19 issuance of the initial report under subsection (g)(6) of
20 section 319 of the Public Health Service Act (42 U.S.C.
21 247d), as added by subsection (a), and again 180 days
22 after the date on which the authority provided under sec-
23 tion 319(g) of such Act expires pursuant to paragraph (7)
24 of such section, the Comptroller General of the United
25 States shall submit to the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives a report on the use of the authority provided
4 under such section. Such report shall, in a manner that
5 protects personal privacy, at a minimum, include informa-
6 tion on—

7 (1) the number of positions publicly noticed and
8 filled under the authority of each of subparagraphs
9 (A) and (B) of such section 319(g)(1);

10 (2) the occupational series, grades, and types of
11 appointments of such positions;

12 (3) how such positions related to addressing a
13 need or shortage described in subparagraph (A) or
14 (B) of such section;

15 (4) how the Secretary of Health and Human
16 Services made appointment decisions under each of
17 subparagraphs (A) and (B) of such section;

18 (5) sources used to identify candidates for fill-
19 ing such positions;

20 (6) the number of individuals appointed under
21 each such subparagraph;

22 (7) aggregated demographic information related
23 to individuals appointed under each such subpara-
24 graph; and

1 (8) any challenges, limitations, or gaps related
2 to the use of the authority under each such subpara-
3 graph and any related recommendations to address
4 such challenges, limitations, or gaps.

5 **SEC. 224. EXTENSION OF AUTHORITIES TO SUPPORT**
6 **HEALTH PROFESSIONAL VOLUNTEERS AT**
7 **COMMUNITY HEALTH CENTERS.**

8 (a) **IN GENERAL.**—Section 224(q) of the Public
9 Health Service Act (42 U.S.C. 233(q)) is amended by
10 striking paragraph (6).

11 (b) **TECHNICAL CORRECTIONS.**—Section 224 of the
12 Public Health Service Act (42 U.S.C. 233) is amended—

13 (1) in subsection (g)(1)(H)(iv), by striking
14 “this section.” and inserting “this section.”;

15 (2) in subsection (k)(3), by inserting “gov-
16 erning board members,” after “officers,”; and

17 (3) in subsection (p)(7)(A)(i), by moving the
18 margin of subclause (II) 2 ems to the left.

19 **SEC. 225. INCREASING EDUCATIONAL OPPORTUNITIES FOR**
20 **ALLIED HEALTH PROFESSIONS.**

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

24 “(4) Increasing educational opportunities in
25 physical therapy, occupational therapy, respiratory

1 therapy, audiology, and speech-language pathology
2 professions, which may include offering scholarships
3 or stipends and carrying out other activities to im-
4 prove retention, for individuals from disadvantaged
5 backgrounds or individuals who are underrep-
6 resented in such professions.”.

7 **SEC. 226. PUBLIC HEALTH SERVICE CORPS ANNUAL AND**
8 **SICK LEAVE.**

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

11 (1) in subsection (a)—

12 (A) by striking “Reserve Corps” and in-
13 serting “Ready Reserve Corps”; and

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

17 (2) by inserting after subsection (a) the fol-
18 lowing:

19 “(b) The regulations described in subsection (a) may
20 authorize accumulated annual leave of not more than 120
21 days for any commissioned officer of the Regular Corps
22 or officer of the Ready Reserve Corps on active duty.”;
23 and

24 (3) by redesignating subsection (d) as sub-
25 section (c).

1 (b) APPLICATION.—The amendments made by sub-
2 section (a) shall apply with respect to accumulated annual
3 leave (as defined in section 219 of the Public Health Serv-
4 ice Act (42 U.S.C. 210–1)) that a commissioned officer
5 of the Regular Corps or officer of the Ready Reserve
6 Corps on active duty would, but for the regulations de-
7 scribed in such section, lose at the end of fiscal year 2022
8 or a subsequent fiscal year.

9 **SEC. 227. ASSESSING BARRIERS TO ADDITIONAL TRAINING.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall evaluate the need for, and identify service-
13 related barriers to, participants of health professional loan
14 repayment programs administered by the Health Re-
15 sources and Services Administration receiving accredited
16 postgraduate training (including internships, fellowships,
17 and residency programs), in non-primary care specialties
18 for which there are workforce shortages, including pallia-
19 tive care.

20 (b) ADDRESSING BARRIERS; REPORT.—The Sec-
21 retary shall—

22 (1) as appropriate, take action to address bar-
23 riers identified under subsection (a); and

24 (2) not later than 2 years after the date of en-
25 actment of this Act, issue a report to the Committee

1 on Health, Education, Labor, and Pensions of the
2 Senate and the Committee on Energy and Com-
3 merce of the House of Representatives on the eval-
4 uation under subsection (a), including—

5 (A) any service-related barriers identified;

6 (B) steps taken to address such barriers
7 under paragraph (1); and

8 (C) as applicable and appropriate, any lim-
9 itations to implementation of actions to address
10 such barriers.

11 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
12 tion shall be construed as in any way affecting, modifying,
13 repealing, or superseding the provisions authorizing health
14 professional loan repayment programs administered by the
15 Health Resources and Services Administration.

16 **SEC. 228. LEADERSHIP EXCHANGE PILOT FOR PUBLIC**
17 **HEALTH AND MEDICAL PREPAREDNESS AND**
18 **RESPONSE POSITIONS AT THE DEPARTMENT**
19 **OF HEALTH AND HUMAN SERVICES.**

20 Title XXVIII of the Public Health Service Act (42
21 U.S.C. 300hh et seq.), as amended by section 214, is fur-
22 ther amended by adding at the end the following:

1 **“SEC. 2826. LEADERSHIP EXCHANGE PILOT FOR PUBLIC**
2 **HEALTH AND MEDICAL PREPAREDNESS AND**
3 **RESPONSE POSITIONS AT THE DEPARTMENT**
4 **OF HEALTH AND HUMAN SERVICES.**

5 “(a) IN GENERAL.—The Secretary may, not later
6 than 1 year after the date of enactment of the PREVENT
7 Pandemics Act, establish a voluntary program to provide
8 additional training to individuals in eligible positions, as
9 described in subsection (c), to support the continuous pro-
10 fessional development of such individuals.

11 “(b) CRITERIA.—

12 “(1) DURATION.—The program under sub-
13 section (a) shall provide for fellowships, details, or
14 other relevant placements with Federal agencies or
15 departments, or State or local health departments,
16 pursuant to the guidance issued under paragraph
17 (2), for a maximum period of 2 years.

18 “(2) GUIDANCE.—The Secretary shall issue
19 guidance establishing criteria for identifying place-
20 ments that demonstrate ongoing sufficient mastery
21 of knowledge, skills, and abilities to satisfy the field
22 experience criteria under the program established
23 under subsection (a), including assignments and ex-
24 periences that develop public health and medical pre-
25 paredness and response expertise.

1 “(c) ELIGIBLE POSITION.—For purposes of sub-
2 section (a), the term ‘eligible position’ means any position
3 at the Department of Health and Human Services at or
4 above grade GS–13 of the General Schedule, or the equiv-
5 alent, for which not less than 50 percent of the time of
6 such position is spent on activities related to public health
7 preparedness or response.

8 “(d) PILOT PERIOD AND FINAL REPORT.—The pilot
9 program authorized under this section shall not exceed 5
10 years. Not later than 90 days after the end of the pro-
11 gram, the Secretary shall issue a report to the Committee
12 on Health, Education, Labor, and Pensions of the Senate
13 and the Committee on Energy and Commerce of the
14 House of Representatives that includes—

15 “(1) the number of individuals who participated
16 in such pilot, as applicable;

17 “(2) a description of the professional growth ex-
18 perience in which individuals participated; and

19 “(3) an assessment of the outcomes of such
20 program, including a recommendation on whether
21 such program should be continued.”.

1 **Subtitle D—Improving Public**
2 **Health Responses**

3 **SEC. 231. CENTERS FOR PUBLIC HEALTH PREPAREDNESS**
4 **AND RESPONSE.**

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

7 (1) by striking subsection (d) and inserting the
8 following:

9 “(d) **CENTERS FOR PUBLIC HEALTH PREPAREDNESS**
10 **AND RESPONSE.**—

11 “(1) **IN GENERAL.**—The Secretary, acting
12 through the Director of the Centers for Disease
13 Control and Prevention, may award grants, con-
14 tracts, or cooperative agreements to institutions of
15 higher education, including accredited schools of
16 public health, or other nonprofit private entities to
17 establish or maintain a network of Centers for Pub-
18 lic Health Preparedness and Response (referred to
19 in this subsection as ‘Centers’).

20 “(2) **ELIGIBILITY.**—To be eligible to receive an
21 award under this subsection, an entity shall submit
22 to the Secretary an application containing such in-
23 formation as the Secretary may require, including a
24 description of how the entity will—

1 “(A) coordinate relevant activities with ap-
2 plicable State, local, and Tribal health depart-
3 ments and officials, health care facilities, and
4 health care coalitions to improve public health
5 preparedness and response, as informed by the
6 public health preparedness and response needs
7 of the community, or communities, involved;

8 “(B) prioritize efforts to implement evi-
9 dence-informed or evidence-based practices to
10 improve public health preparedness and re-
11 sponse, including by helping to reduce the
12 transmission of emerging infectious diseases;
13 and

14 “(C) use funds awarded under this sub-
15 section, including by carrying out any activities
16 described in paragraph (3).

17 “(3) USE OF FUNDS.—The Centers established
18 or maintained under this subsection shall use funds
19 awarded under this subsection to carry out activities
20 to advance public health preparedness and response
21 capabilities, which may include—

22 “(A) identifying, translating, and dissemi-
23 nating promising research findings or strategies
24 into evidence-informed or evidence-based prac-
25 tices to inform preparedness for, and responses

1 to, chemical, biological, radiological, or nuclear
2 threats, including emerging infectious diseases,
3 and other public health emergencies, which may
4 include conducting research related to public
5 health preparedness and response systems;

6 “(B) improving awareness of such evi-
7 dence-informed or evidence-based practices and
8 other relevant scientific or public health infor-
9 mation among health care professionals, public
10 health professionals, other stakeholders, and the
11 public, including through the development, eval-
12 uation, and dissemination of trainings and
13 training materials, consistent with section
14 2802(b)(2), as applicable and appropriate, and
15 with consideration given to existing training
16 materials, to support preparedness for, and re-
17 sponses to, such threats;

18 “(C) utilizing and expanding relevant tech-
19 nological and analytical capabilities to inform
20 public health and medical preparedness and re-
21 sponse efforts;

22 “(D) expanding activities, including
23 through public-private partnerships, related to
24 public health preparedness and response, in-
25 cluding participation in drills and exercises and

1 training public health experts, as appropriate;
2 and

3 “(E) providing technical assistance and ex-
4 pertise that relies on evidence-based practices,
5 as applicable, related to responses to public
6 health emergencies, as appropriate, to State,
7 local, and Tribal health departments and other
8 entities pursuant to paragraph (2)(A).

9 “(4) DISTRIBUTION OF AWARDS.—In awarding
10 grants, contracts, or cooperative agreements under
11 this subsection, the Secretary shall support not
12 fewer than 10 Centers, subject to the availability of
13 appropriations, and ensure that such awards are eq-
14 uitably distributed among the geographical regions
15 of the United States.”; and

16 (2) in subsection (f)(1)(C), by striking “, of
17 which \$5,000,000 shall be used to carry out para-
18 graphs (3) through (5) of such subsection”.

19 (b) REPEAL.—Section 319G of the Public Health
20 Service Act (42 U.S.C. 247d–7) is repealed.

21 **SEC. 232. VACCINE DISTRIBUTION PLANS.**

22 Section 319A of the Public Health Service Act (42
23 U.S.C. 247d–1) is amended—

24 (1) in subsection (a)—

1 (A) by inserting “, or other federally pur-
2 chased vaccine to address another pandemic”
3 before the period at the end of the first sen-
4 tence; and

5 (B) by inserting “or other pandemic” be-
6 fore the period at the end of the second sen-
7 tence; and

8 (2) in subsection (d), by inserting “or other
9 pandemics” after “influenza pandemics”.

10 **SEC. 233. COORDINATION AND COLLABORATION REGARD-**
11 **ING BLOOD SUPPLY.**

12 (a) IN GENERAL.—The Secretary of Health and
13 Human Services, or the Secretary’s designee, shall—

14 (1) ensure coordination and collaboration be-
15 tween relevant Federal departments and agencies re-
16 lated to the safety and availability of the blood sup-
17 ply, including—

18 (A) the Department of Health and Human
19 Services, including the Office of the Assistant
20 Secretary for Health, the Centers for Disease
21 Control and Prevention, the Food and Drug
22 Administration, the Office of the Assistant Sec-
23 retary for Preparedness and Response, the Na-
24 tional Institutes of Health, the Centers for

1 Medicare & Medicaid Services, and the Health
2 Resources and Services Administration;

3 (B) the Department of Defense; and

4 (C) the Department of Veterans Affairs;

5 and

6 (2) consult and communicate with private
7 stakeholders, including blood collection establish-
8 ments, health care providers, accreditation organiza-
9 tions, researchers, and patients, regarding issues re-
10 lated to the safety and availability of the blood sup-
11 ply.

12 (b) STREAMLINING BLOOD DONOR INPUT.—Chapter
13 35 of title 44, United States Code, shall not apply to the
14 collection of information to which a response is voluntary
15 and that is initiated by the Secretary of Health and
16 Human Services to solicit information from blood donors
17 or potential blood donors to support the development of
18 recommendations by the Secretary concerning blood dona-
19 tion.

20 **SEC. 234. SUPPORTING LABORATORY CAPACITY AND**
21 **INTERNATIONAL COLLABORATION TO AD-**
22 **DRESS ANTIMICROBIAL RESISTANCE.**

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

1 (1) by redesignating subsections (k), (l), and
2 (m) as subsections (m), (n), and (o), respectively;
3 and

4 (2) by inserting after subsection (j), the fol-
5 lowing:

6 “(k) NETWORK OF ANTIBIOTIC RESISTANCE RE-
7 GIONAL LABORATORIES.—

8 “(1) IN GENERAL.—The Secretary, acting
9 through the Director of the Centers for Disease
10 Control and Prevention, shall, as appropriate, main-
11 tain a network of antibiotic resistance laboratory
12 sites to ensure the maintenance of appropriate capa-
13 bilities, within existing laboratory capacity main-
14 tained or supported by the Centers for Disease Con-
15 trol and Prevention, to—

16 “(A) identify and monitor the emergence
17 and changes in the patterns of antimicrobial-re-
18 sistant pathogens;

19 “(B) detect, identify, confirm, and isolate
20 such resistant pathogens, including, as appro-
21 priate, performing such activities upon the re-
22 quest of another laboratory and providing re-
23 lated technical assistance, and, as applicable,
24 support efforts to respond to local or regional
25 outbreaks of such resistant pathogens; and

1 “(C) perform activities to support the diag-
2 nosis of such resistant pathogens and determine
3 the susceptibility of relevant pathogen samples
4 to applicable treatments.

5 “(2) GEOGRAPHIC DISTRIBUTION.—The Sec-
6 retary shall ensure that such capacity and capabili-
7 ties are appropriately distributed among the geo-
8 graphical regions of the United States.

9 “(3) PARTNERSHIPS AND NONDUPLICATION OF
10 CURRENT DOMESTIC CAPACITY.—Activities sup-
11 ported under this subsection may be based in an
12 academic center, a State health department, or other
13 facility operated by a public or private entity that
14 carries out relevant laboratory or public health sur-
15 veillance activities.

16 “(1) INTERNATIONAL COLLABORATION.—

17 “(1) IN GENERAL.—The Secretary, in coordina-
18 tion with heads of other relevant Federal depart-
19 ments and agencies, shall support activities related
20 to addressing antimicrobial resistance internation-
21 ally, including by—

22 “(A) supporting basic, translational, epide-
23 miological, and clinical research related to anti-
24 microbial-resistant pathogens, including such
25 pathogens that have not yet been detected in

1 the United States, and improving related public
2 health surveillance systems, and laboratory and
3 other response capacity; and

4 “(B) providing technical assistance related
5 to antimicrobial resistant infection and control
6 activities.

7 “(2) AWARDS.—In carrying out paragraph (1),
8 the Secretary may award grants, contracts, or coop-
9 erative agreements to public and private entities, in-
10 cluding nongovernmental organizations, with appli-
11 cable expertise, for purposes of supporting new and
12 innovative approaches to the prevention, detection,
13 and mitigation of antimicrobial-resistant patho-
14 gens.”.

15 **SEC. 235. ONE HEALTH FRAMEWORK.**

16 (a) ONE HEALTH FRAMEWORK.—The Secretary of
17 Health and Human Services (referred to in this section
18 as the “Secretary”), acting through the Director of the
19 Centers for Disease Control and Prevention, shall develop,
20 or update as appropriate, in coordination with other Fed-
21 eral departments and agencies, as appropriate, a One
22 Health framework to address zoonotic diseases and ad-
23 vance public health preparedness.

24 (b) ONE HEALTH COORDINATION.—The Secretary,
25 acting through the Director of the Centers for Disease

1 Control and Prevention, shall coordinate with the Sec-
2 retary of Agriculture and the Secretary of the Interior to
3 develop a One Health coordination mechanism at the Fed-
4 eral level to strengthen One Health collaboration related
5 to prevention, detection, control, and response for zoonotic
6 diseases and related One Health work across the Federal
7 Government.

8 (c) REPORTING.—Not later than 1 year after the date
9 of enactment of this Act, the Secretary shall submit to
10 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 pro-
13 viding an update on the activities under subsections (a)
14 and (b).

15 **SEC. 236. SUPPORTING CHILDREN DURING PUBLIC**
16 **HEALTH EMERGENCIES.**

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

19 (1) in subsection (b)—

20 (A) in paragraph (2)—

21 (i) by striking “and behavioral” and
22 inserting “, behavioral, developmental”;
23 and

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

1 (B) in paragraph (3), by striking the pe-
2 riod and inserting “; and”; and

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

4 “(4) provide advice and consultation with re-
5 spect to continuity of care and education for all chil-
6 dren and supporting parents and caregivers during
7 all-hazards emergencies.”;

8 (2) in subsection (d)(2)—

9 (A) in subparagraph (C), by striking
10 “care; and” and inserting “care;”;

11 (B) by redesignating subparagraph (D) as
12 subparagraph (E);

13 (C) by inserting after subparagraph (C)
14 the following:

15 “(D) at least 4 non-Federal members rep-
16 resenting child care settings, State or local edu-
17 cational agencies, individuals with expertise in
18 children with disabilities, and parents; and”;
19 and

20 (D) in subparagraph (E), as so redesi-
21 gnated—

22 (i) by striking clause (ii); and

23 (ii) by redesignating clauses (iii) and

24 (iv) as clauses (ii) and (iii), respectively.

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) coordinate activities among relevant Federal
14 departments and agencies with respect to addressing
15 the long-term health effects of SARS-CoV-2 infec-
16 tion, which may include conditions that arise as a
17 result of such infection;

18 (2) continue to conduct or support basic, clin-
19 ical, epidemiological, behavioral, and translational
20 research and public health surveillance related to the
21 pathogenesis, prevention, diagnosis, and treatment
22 of the long-term health effects of SARS-CoV-2 in-
23 fection, which may include conditions that arise as
24 a result of such infection; and

1 (3) consistent with the findings of studies and
2 research under paragraph (1), in consultation with
3 health professional associations, scientific and med-
4 ical researchers, and other relevant experts, develop
5 and inform recommendations, guidance, and edu-
6 cational materials on the long-term effects of SARS-
7 CoV-2 infection, which may include conditions that
8 arise as a result of such infection, and provide such
9 recommendations, guidance, and educational mate-
10 rials to health care providers and the general public.

11 (b) CONSIDERATIONS.—In conducting or supporting
12 research under this section, the Secretary shall consider
13 the diversity of research participants or cohorts to ensure
14 inclusion of a broad range of participants, as applicable
15 and appropriate.

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

17 (1) direct the Director of the Agency for
18 Healthcare Research and Quality to—

19 (A) assist in the identification and develop-
20 ment of evidence regarding the delivery of high-
21 quality, high-value health care for individuals
22 experiencing long-term health effects of SARS-
23 CoV-2, which may include conditions that arise
24 as a result of such infection;

1 (B) develop or identify tools and strategies
2 to help health care entities and providers care
3 for such populations; and

4 (C) disseminate such evidence, tools, and
5 strategies; and

6 (2) establish a primary care technical assistance
7 initiative to convene primary care providers and or-
8 ganizations in order to collect and disseminate best
9 practices related to the care of individuals with long-
10 term health effects of SARS-CoV-2 infection, which
11 may include conditions that arise as a result of such
12 infection.

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

24 (e) PUBLIC AVAILABILITY OF INFORMATION.—In
25 making information or reports publicly available under

1 this section, the Secretary shall take into consideration the
2 delivery of such information in a manner that takes into
3 account the range of communication needs of the intended
4 recipients, including at-risk individuals.

5 **SEC. 302. RESEARCH CENTERS FOR PATHOGENS OF PAN-**
6 **DEMIC CONCERN.**

7 Subpart 6 of part C of title IV of the Public Health
8 Service Act is amended by inserting after section 447C
9 (42 U.S.C. 285f-4) the following:

10 **“SEC. 447D. RESEARCH CENTERS FOR PATHOGENS OF PAN-**
11 **DEMIC CONCERN.**

12 “(a) IN GENERAL.—The Director of the Institute, in
13 collaboration, as appropriate, with the directors of applica-
14 ble institutes, centers, and divisions of the National Insti-
15 tutes of Health, the Assistant Secretary for Preparedness
16 and Response, and the Director of the Biomedical Ad-
17 vanced Research and Development Authority, shall estab-
18 lish or continue a multidisciplinary research program to
19 advance the discovery and preclinical development of med-
20 ical products for priority virus families and other viral
21 pathogens with a significant potential to cause a pan-
22 demic, through support for research centers.

23 “(b) USES OF FUNDS.—The Director of the Institute
24 shall award funding through grants, contracts, or coopera-
25 tive agreements to public or private entities to provide

1 support for research centers described in subsection (a)
2 for the purpose of—

3 “(1) conducting basic research through pre-
4 clinical development of new medical products or
5 technologies, including platform technologies, to ad-
6 dress pathogens of pandemic concern;

7 “(2) identifying potential targets for thera-
8 peutic candidates, including antivirals, to treat such
9 pathogens;

10 “(3) identifying existing medical products with
11 the potential to address such pathogens, including
12 candidates that could be used in outpatient settings;
13 and

14 “(4) carrying out or supporting other research
15 related to medical products to address such patho-
16 gens, as determined appropriate by the Director.

17 “(c) COORDINATION.—The Director of the Institute
18 shall, as appropriate, provide for the coordination of ac-
19 tivities among the centers described in subsection (a), in-
20 cluding through—

21 “(1) facilitating the exchange of information
22 and regular communication among the centers, as
23 appropriate; and

1 “(2) requiring the periodic preparation and sub-
2 mission to the Director of reports on the activities
3 of each center.

4 “(d) PRIORITY.—In awarding funding through
5 grants, contracts, or cooperative agreements under sub-
6 section (a), the Director of the Institute shall, as appro-
7 priate, give priority to applicants with existing frameworks
8 and partnerships, as applicable, to support the advance-
9 ment of such research.

10 “(e) COLLABORATION.—The Director of the Institute
11 shall—

12 “(1) collaborate with the heads of other appro-
13 priate Federal departments, agencies, and offices
14 with respect to the identification of additional pri-
15 ority virus families and other viral pathogens with a
16 significant potential to cause a pandemic; and

17 “(2) collaborate with the Director of the Bio-
18 medical Advanced Research and Development Au-
19 thority with respect to the research conducted by
20 centers described in subsection (a), including, as ap-
21 propriate, providing any updates on the research ad-
22 vancements made by such centers, identifying any
23 advanced research and development needs for such
24 countermeasures, consistent with section
25 319L(a)(6), and taking into consideration existing

1 manufacturing capacity and future capacity needs
2 for such medical products or technologies, including
3 platform technologies, supported by the centers de-
4 scribed in subsection (a).

5 “(f) SUPPLEMENT, NOT SUPPLANT.—Any support
6 received by a center described in subsection (a) under this
7 section shall be used to supplement, and not supplant,
8 other public or private support for activities authorized to
9 be supported.”.

10 **SEC. 303. IMPROVING MEDICAL COUNTERMEASURE RE-**
11 **SEARCH COORDINATION.**

12 Section 402(b) in the Public Health Service Act (42
13 U.S.C. 282(b)) is amended—

14 (1) in paragraph (24), by striking “and” at the
15 end;

16 (2) in paragraph (25), by striking the period
17 and inserting a semicolon; and

18 (3) by inserting after paragraph (25) the fol-
19 lowing:

20 “(26) shall consult with the Assistant Secretary
21 for Preparedness and Response, the Director of the
22 Biomedical Advanced Research and Development
23 Authority, the Director of the Centers for Disease
24 Control and Prevention, and the heads of other Fed-
25 eral agencies and offices, as appropriate, regarding

1 research needs to advance medical countermeasures
2 to diagnose, mitigate, prevent, or treat harm from
3 any biological agent or toxin, including emerging in-
4 fectionous diseases, chemical, radiological, or nuclear
5 agent that may cause a public health emergency or
6 other research needs related to emerging public
7 health threats;”.

8 **SEC. 304. ACCESSING SPECIMEN SAMPLES AND DIAG-**
9 **NOSTIC TESTS.**

10 (a) IMPROVING RESEARCH AND DEVELOPMENT OF
11 MEDICAL COUNTERMEASURES FOR NOVEL PATHO-
12 GENS.—

13 (1) SAMPLE ACCESS.—Not later than 1 year
14 after the date of enactment of this Act, the Sec-
15 retary of Health and Human Services (referred to in
16 this subsection as the “Secretary”) shall make pub-
17 licly available policies and procedures related to pub-
18 lic and private entities accessing specimens of, or
19 specimens containing, pathogens or suitable surro-
20 gates for, or alternatives to, such pathogens as the
21 Secretary determines appropriate to support public
22 health preparedness and response activities or bio-
23 medical research for purposes of the development
24 and validation, as applicable, of medical products to
25 address emerging infectious diseases and for use to

1 otherwise respond to emerging infectious diseases.
2 Such policies and procedures shall take into account,
3 as appropriate, any applicable existing Federal re-
4 sources.

5 (2) GUIDANCE.—The Secretary shall issue
6 guidance regarding the procedures for carrying out
7 paragraph (1), including—

8 (A) the method for requesting such sam-
9 ples;

10 (B) considerations for sample availability
11 and use of suitable surrogates or alternatives to
12 such pathogens, as appropriate, including appli-
13 cable safeguard and security measures; and

14 (C) information required to be provided in
15 order to receive such samples or suitable surro-
16 gates or alternatives.

17 (b) EARLIER DEVELOPMENT OF DIAGNOSTIC
18 TESTS.—Title III of the Public Health Service Act is
19 amended by inserting after section 319A (42 U.S.C.
20 247d–1) the following:

21 **“SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC**
22 **TESTS.**

23 “The Secretary may contract with public and private
24 entities, as appropriate, to increase capacity in the rapid
25 development, validation, manufacture, and dissemination

1 of diagnostic tests, as appropriate, to State, local, and
2 Tribal health departments and other appropriate entities
3 for immediate public health response activities to address
4 an emerging infectious disease with respect to which a
5 public health emergency is declared under section 319, or
6 that has significant potential to cause such a public health
7 emergency.”.

8 **SEC. 305. NATIONAL ACADEMIES OF SCIENCES, ENGINEER-**
9 **ING, AND MEDICINE STUDY ON NATURAL IM-**
10 **MUNITY IN RELATION TO THE COVID-19 PAN-**
11 **DEMIC.**

12 (a) IN GENERAL.—Not later than 45 days after the
13 date of enactment of this Act, the Secretary of Health and
14 Human Services shall seek to enter into a contract with
15 the National Academies of Sciences, Engineering, and
16 Medicine (referred to in this section as the “National
17 Academies”) to conduct a study related to the current sci-
18 entific evidence on the durability of immunity to COVID-
19 19.

20 (b) INCLUSIONS.—The study pursuant to the con-
21 tract under subsection (a) shall include—

22 (1) an assessment of scientific evidence related
23 to the durability of immunity resulting from SARS-
24 CoV-2 infection, COVID-19 vaccination, or both,
25 including any differences between population groups;

1 (2) an assessment of the extent to which the
2 Federal Government makes publicly available the
3 scientific evidence used by relevant Federal depart-
4 ments and agencies to inform public health rec-
5 ommendations related to immunity resulting from
6 SARS-CoV-2 infection and COVID-19 vaccination;
7 and

8 (3) a summary of scientific studies and evidence
9 related to SARS-CoV-2 infection-acquired immunity
10 from a sample of other countries or multilateral or-
11 ganizations.

12 (c) REPORT.—Not later than 18 months after the
13 date of enactment of this Act, the National Academies
14 shall submit to the Committee on Health, Education,
15 Labor, and Pensions of the Senate and the Committee on
16 Energy and Commerce of the House of Representatives
17 a report on the study pursuant to subsection (a).

18 (d) AUTHORIZATION OF APPROPRIATION.—There is
19 authorized to be appropriated such sums as may be nec-
20 essary for fiscal year 2023 to carry out this section.

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 operating at Biosafety
5 Level 3 or 4, including equivalent classification levels and
6 facilities with Biosafety Level 4 capabilities. Such strategy
7 shall include—

8 (1) a description of the roles and responsibil-
9 ities of relevant Federal departments and agencies
10 with respect to the management, maintenance, and
11 oversight of Biosafety Level 3 or 4 laboratory facili-
12 ties;

13 (2) an assessment of the needs of the Federal
14 Government with respect to Biosafety Level 3 or 4
15 laboratory facilities;

16 (3) a summary of existing federally-owned Bio-
17 safety Level 3 or 4 laboratory facility capacity;

18 (4) a summary of other Biosafety Level 3 or 4
19 laboratory facility capacity established through Fed-
20 eral funds;

21 (5) a description of how the capacity described
22 in paragraphs (3) and (4) addresses the needs of the
23 Federal Government, including—

24 (A) how relevant Federal departments and
25 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 Federal depart-
17 ments and agencies in order to reduce unnecessary
18 duplication and improve collaboration within the
19 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 year after the date of
21 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 enhanced patho-
2 gens of pandemic 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 guidance to implement the requirements
18 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 (a) INTRAMURAL RESEARCH.—

6 (1) IN GENERAL.—Not later than 60 days after
7 the date of enactment of this Act, the Secretary of
8 Health and Human Services (referred to in this sec-
9 tion as the “Secretary”) shall prohibit personnel of
10 the National Institutes of Health engaged in intra-
11 mural research from participation in foreign talent
12 programs.

13 (2) EXEMPTION.—Paragraph (1) shall not
14 apply to participation in international conferences or
15 other international exchanges, partnerships, or pro-
16 grams, for which such participation has been ap-
17 proved by the National Institutes of Health. In such
18 circumstances, the National Institutes of Health
19 shall ensure appropriate training is provided to the
20 participant on how to respond to overtures from in-
21 dividuals associated with foreign talent programs.

22 (b) EXTRAMURAL RESEARCH.—The Secretary shall
23 require disclosure of participation in foreign talent pro-
24 grams, including the provision of copies of all grants, con-
25 tracts, or other agreements related to such programs, and

1 other supporting documentation related to such programs,
2 as a condition of receipt of Federal extramural biomedical
3 research funding awarded through the Department of
4 Health and Human Services.

5 **SEC. 322. SECURING IDENTIFIABLE, SENSITIVE INFORMA-**
6 **TION AND ADDRESSING OTHER NATIONAL**
7 **SECURITY RISKS RELATED TO RESEARCH.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”), in consultation with the Director of National In-
11 telligence, the Secretary of State, the Secretary of De-
12 fense, and other national security experts, as appropriate,
13 shall ensure that biomedical research conducted or sup-
14 ported by the National Institutes of Health and other rel-
15 evant agencies and offices within the Department of
16 Health and Human Services is conducted or supported in
17 a manner that appropriately considers national security
18 risks, including national security implications related to
19 research involving the sequencing of human genomic infor-
20 mation, and collection, analysis, or storage of identifiable,
21 sensitive information, as defined in section 301(d)(4) of
22 the Public Health Service Act (42 U.S.C. 241(d)(4)), and
23 the potential misuse of such data. Not later than 2 years
24 after the date of enactment of this Act, the Secretary shall
25 ensure that the National Institutes of Health and other

1 relevant agencies and offices within the Department of
2 Health and Human Services, working with the heads of
3 agencies and national security experts, including the Of-
4 fice of the National Security within the Department of
5 Health and Human Services—

6 (1) develop a comprehensive framework for as-
7 sessing and managing such national security risks
8 that includes—

9 (A) criteria for how and when to conduct
10 risk assessments for projects that may have na-
11 tional security implications;

12 (B) security controls and training for re-
13 searchers or entities, including peer reviewers,
14 that manage or have access to such data that
15 may present national security risks; and

16 (C) methods to incorporate risk mitigation
17 in the process for funding such projects that
18 may have national security implications and
19 monitor associated research activities following
20 issuance of an award, including changes in the
21 terms and conditions related to the use of such
22 funds, as appropriate;

23 (2) not later than 1 year after the risk frame-
24 work is developed under paragraph (1), develop and
25 implement controls to ensure that—

1 (A) researchers or entities involved in
2 projects reviewed under the risk framework, in-
3 cluding such projects that manage or have ac-
4 cess to sensitive, identifiable information, have
5 complied with the requirements of paragraph
6 (1) and ongoing requirements with such para-
7 graph;

8 (B) consideration of funding for projects
9 that may have national security implications
10 takes into account the extent to which the coun-
11 try in which the proposed research will be con-
12 ducted or supported poses a risk to the integ-
13 rity of the United States biomedical research
14 enterprise; and

15 (C) data access committees reviewing data
16 access requests for projects that may have na-
17 tional security risks, as appropriate, include
18 members with expertise in current and emerg-
19 ing national security threats, in order to make
20 appropriate decisions, including related to ac-
21 cess to such identifiable, sensitive information;
22 and

23 (3) not later than 2 years after the risk frame-
24 work is developed under paragraph (1), update data
25 access and sharing policies related to human

1 genomic data, as appropriate, based on current and
2 emerging national security threats.

3 (b) CONGRESSIONAL BRIEFING.—Not later than 1
4 year after the date of enactment of this Act, the Secretary
5 shall provide a briefing to the Committee on Health, Edu-
6 cation, Labor, and Pensions and the Select Committee on
7 Intelligence of the Senate and the Committee on Energy
8 and Commerce and the Permanent Select Committee on
9 Intelligence of the House of Representatives on the activi-
10 ties required under subsection (a).

11 **SEC. 323. DUTIES OF THE DIRECTOR.**

12 Section 402(b) in the Public Health Service Act (42
13 U.S.C. 282(b)), as amended by section 303, is further
14 amended by inserting after paragraph (26) (as added by
15 section 303) the following:

16 “(27) shall consult with the Director of the Of-
17 fice of National Security within the Department of
18 Health and Human Services, the Assistant Secretary
19 for Preparedness and Response, the Director of Na-
20 tional Intelligence, the Director of the Federal Bu-
21 reau of Investigation, and the heads of other appro-
22 priate agencies on a regular basis, regarding bio-
23 medical research conducted or supported by the Na-
24 tional Institutes of Health that may affect or be af-
25 fected by matters of national security;

1 “(28) shall ensure that recipients of awards
2 from the National Institutes of Health, and, as ap-
3 propriate and practicable, entities collaborating with
4 such recipients, have in place and are adhering to
5 appropriate technology practices and policies for the
6 security of identifiable, sensitive information, includ-
7 ing information collected, stored, or analyzed by do-
8 mestic and non-domestic entities; and

9 “(29) shall ensure that recipients of awards
10 from the National Institutes of Health are in compli-
11 ance with the terms and conditions of such award,
12 which may include activities to support awareness of,
13 and compliance with, such terms and conditions by
14 any subrecipients of the award.”.

15 **SEC. 324. PROTECTING AMERICA’S BIOMEDICAL RESEARCH**
16 **ENTERPRISE.**

17 (a) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this section as the “Sec-
19 retary”), in collaboration with Assistant to the President
20 for National Security Affairs, the Director of National In-
21 telligence, the Director of the Federal Bureau of Inves-
22 tigation, and the heads of other relevant departments and
23 agencies, and in consultation with research institutions
24 and research advocacy organizations or other relevant ex-
25 perts, as appropriate, shall—

1 (1) identify ways to improve the protection of
2 intellectual property and other proprietary informa-
3 tion, as well as identifiable, sensitive information of
4 participants in biomedical research and development,
5 from national security risks and other applicable
6 threats, including the identification of gaps in poli-
7 cies and procedures in such areas related to bio-
8 medical research and development supported by the
9 Department of Health and Human Services and bio-
10 medical research supported by other agencies as ap-
11 plicable, and make recommendations to institutions
12 of higher education or other entities that have tradi-
13 tionally received Federal funding for biomedical re-
14 search to protect such information;

15 (2) identify or develop strategies to prevent,
16 mitigate, and address national security threats in
17 biomedical research and development supported by
18 the Federal Government, including such threats as-
19 sociated with foreign talent programs, by countries
20 seeking to exploit United States technology and
21 other proprietary information as it relates to such
22 biomedical research and development;

23 (3) identify national security risks and potential
24 misuse of proprietary information, and identifiable,
25 sensitive information of biomedical research partici-

1 pants and other applicable risks, including with re-
2 spect to peer review, and make recommendations for
3 additional policies and procedures to protect such in-
4 formation;

5 (4) develop a framework to identify areas of
6 biomedical research and development supported by
7 the Federal Government that are emerging areas of
8 interest for state actors and would compromise na-
9 tional security if they were to be subjected to undue
10 foreign influence; and

11 (5) regularly review recommendations or poli-
12 cies developed under this section and make addi-
13 tional recommendations or updates, as appropriate.

14 (b) REPORT TO PRESIDENT AND TO CONGRESS.—
15 Not later than 1 year after the date of enactment of this
16 Act, the Secretary shall prepare and submit, in a manner
17 that does not compromise national security, to the Presi-
18 dent and the Committee on Health, Education, Labor, and
19 Pensions and the Select Committee on Intelligence of the
20 Senate, the Committee on Energy and Commerce and the
21 Permanent Select Committee on Intelligence of the House
22 of Representatives, and other congressional committees as
23 appropriate, a report on the findings and recommenda-
24 tions pursuant to subsection (a).

1 **SEC. 325. GAO STUDY.**

2 (a) IN GENERAL.—The Comptroller General of the
3 United States (referred to in this section as the “Comp-
4 troller General”) shall conduct a study to assess the extent
5 to which the Department of Health and Human Services
6 (referred to in this section as the “Department”) utilizes
7 or provides funding to entities that utilize such funds for
8 human genomic sequencing services or genetic services (as
9 such term is defined in section 201(6) of the Genetic In-
10 formation Nondiscrimination Act of 2008 (42 U.S.C.
11 2000ff(6))) provided by entities, or subsidiaries of such
12 entities, organized under the laws of a country or coun-
13 tries of concern, in the estimation of the Director of Na-
14 tional Intelligence or the head of another Federal depart-
15 ment or agency, as appropriate.

16 (b) CONSIDERATIONS.—In carrying out the study
17 under this section, the Comptroller General shall—

18 (1) consider—

19 (A) the extent to which the country or
20 countries of concern could obtain human
21 genomic information of citizens and residents of
22 the United States from such entities that se-
23 quence, analyze, collect, or store human
24 genomic information and which the Director of
25 National Intelligence or the head of another
26 Federal department or agency reasonably an-

1 ticipates may use such information in a manner
2 inconsistent with the national security interests
3 of the United States;

4 (B) whether the Department or recipient
5 of such funds from the Department sought to
6 provide funding to, or to use, domestic entities
7 with no such ties to the country or countries of
8 concern for such purposes and any barriers to
9 the use of domestic entities; and

10 (C) whether data use agreements, data se-
11 curity measures, and other such measures taken
12 by the Department or recipient of such funds
13 from the Department are sufficient to protect
14 the identifiable, sensitive information of the
15 people of the United States and the national se-
16 curity interests of the United States; and

17 (2) make recommendations to address any
18 vulnerabilities to the United States national security
19 identified, as appropriate.

20 (c) ESTIMATION.—In conducting the study under this
21 section, the Comptroller General may, as appropriate and
22 necessary to complete such study, investigate specific in-
23 stances of such utilization of genetic sequencing services
24 or genetic services, as described in subsection (a), to

1 produce estimates of the potential prevalence of such utili-
2 zation among entities in receipt of Departmental funds.

3 (d) REPORT.—Not later than 2 years after the date
4 of enactment of this Act, the Comptroller General shall
5 submit a report on the study under this section, in a man-
6 ner that does not compromise national security, to the
7 Committee on Health, Education, Labor, and Pensions
8 and the Select Committee on Intelligence of the Senate,
9 and the Committee on Energy and Commerce and the Per-
10 manent Select Committee on Intelligence of the House of
11 Representatives. The report shall be submitted in unclassi-
12 fied form, to the extent practicable, but may include a
13 classified annex.

14 **SEC. 326. REPORT ON PROGRESS TO ADDRESS UNDUE FOR-**
15 **EIGN INFLUENCE.**

16 Not later than 1 year after the date of enactment
17 of this Act and annually thereafter, the Secretary of
18 Health and Human Services shall prepare and submit to
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce in the House of Representatives, in a manner
22 that does not compromise national security, a report on
23 actions taken by such Secretary—

1 (1) to address cases of noncompliance with dis-
2 closure requirements or research misconduct related
3 to foreign influence, including—

4 (A) the number of potential noncompliance
5 cases investigated by the National Institutes of
6 Health or reported to the National Institutes of
7 Health by a research institution, including re-
8 lating to undisclosed research support, undis-
9 closed conflicts of interest or other conflicts of
10 commitment, and peer review violations;

11 (B) the number of cases referred to the
12 Office of Inspector General of the Department
13 of Health and Human Services, the Office of
14 National Security of the Department of Health
15 and Human Services, the Federal Bureau of In-
16 vestigation, or other law enforcement agencies;

17 (C) a description of enforcement actions
18 taken for noncompliance related to undue for-
19 eign influence; and

20 (D) any other relevant information; and

21 (2) to prevent, address, and mitigate instances
22 of noncompliance with disclosure requirements or re-
23 search misconduct related to foreign influence.

1 **Subtitle D—Advanced Research**
2 **Projects Authority for Health**

3 **SEC. 331. ADVANCED RESEARCH PROJECTS AUTHORITY**
4 **FOR HEALTH.**

5 Part E of title IV of the Public Health Service Act
6 (42 U.S.C. 287 et seq.) is amended by inserting after sub-
7 part 2 of such part the following:

8 **“Subpart 3—Advanced Research Projects Authority**
9 **for Health**

10 **“SEC. 483. ADVANCED RESEARCH PROJECTS AUTHORITY**
11 **FOR HEALTH.**

12 “(a) DEFINITIONS.—In this section:

13 “(1) ARPA–H.—The term ‘ARPA–H’ means
14 the Advanced Research Projects Authority for
15 Health established under subsection (b).

16 “(2) DIRECTOR.—The term ‘Director’ means
17 the Director of ARPA–H appointed under sub-
18 section (c).

19 “(3) OTHER TRANSACTIONS.—The term ‘other
20 transactions’ has the meaning given such term in
21 section 319L(a)(3).

22 “(b) ESTABLISHMENT OF THE ADVANCED RE-
23 SEARCH PROJECTS AUTHORITY FOR HEALTH.—There is
24 established within the National Institutes of Health the

1 Advanced Research Projects Authority for Health, for
2 purposes of—

3 “(1) supporting high-impact, cutting-edge re-
4 search in biomedicine and broadly applicable break-
5 through technologies that have the potential to sig-
6 nificantly transform and advance areas of biomedical
7 science and medicine in a manner that cannot read-
8 ily be accomplished through traditional biomedical
9 research or commercial activity; and

10 “(2) overcoming long-term and significant tech-
11 nological and scientific barriers to advancing such
12 technologies in order to improve the prevention, di-
13 agnosis, mitigation, treatment, and cure of health
14 conditions.

15 “(c) DIRECTOR.—

16 “(1) IN GENERAL.—ARPA–H shall be headed
17 by a Director, who shall be appointed by the Presi-
18 dent. The Director shall report to the Director of
19 NIH.

20 “(2) QUALIFICATIONS.—The Director shall be
21 an individual who, by reason of professional back-
22 ground and experience, is especially qualified to ad-
23 vise the Secretary on, and manage, research pro-
24 grams that advance the purposes of ARPA–H in
25 promoting biomedical and novel technology innova-

1 tion pursuant to this section, and who has a dem-
2 onstrated ability to identify and develop partnerships
3 to address strategic needs in meeting such purposes.

4 “(3) APPOINTMENT.—Notwithstanding section
5 405(a)(2), the Director shall be appointed for a pe-
6 riod of 4 years. The President may extend the term
7 of a Director for a period of up to 4 additional
8 years.

9 “(4) DUTIES.—The Director shall—

10 “(A) establish strategic goals, objectives,
11 and priorities for ARPA–H, pursuant to the
12 purposes of ARPA–H described in subsection
13 (b);

14 “(B) approve all new programs within
15 ARPA–H and terminate any program within
16 ARPA–H that is not achieving its goals;

17 “(C) establish criteria for funding and as-
18 sessing the success of programs through the es-
19 tablishment of technical milestones;

20 “(D) ensure that applications for funding
21 disclose current and previous research and de-
22 velopment efforts, and identify any challenges
23 associated with such efforts, including any sci-
24 entific or technical barriers encountered in the
25 course of such efforts or challenges in securing

1 sources of funding, as applicable and appro-
2 priate, in pursuit of the technology area for
3 which funding is requested;

4 “(E) facilitate coordination between the
5 Department of Health and Human Services,
6 relevant agencies within such Department, and
7 other relevant Federal departments and agen-
8 cies, with respect to research supported by
9 ARPA-H;

10 “(F) support transformative, translational,
11 applied, and advanced research in areas of bio-
12 medical science to address specific technical or
13 scientific questions by —

14 “(i) prioritizing investments based on
15 scientific potential and impact on the field
16 of biomedicine, as described in subsection
17 (b), especially in areas that require public-
18 private partnerships in order to effectively
19 advance research and development activi-
20 ties;

21 “(ii) translating scientific discoveries
22 and cutting-edge innovation into techno-
23 logical advancements;

1 “(iii) encouraging opportunities to de-
2 velop broadly applicable technologies, using
3 a multi-disciplinary approach; and

4 “(iv) making investments in high-risk,
5 high-reward research related to broadly ap-
6 plicable technologies, capabilities, and plat-
7 forms that may have an application for
8 medicine and health;

9 “(G) encourage strategic collaboration and
10 partnerships with a broad range of entities, in-
11 cluding institutions of higher education, indus-
12 try, nonprofit organizations, or consortia of
13 such entities, which may include federally-fund-
14 ed research and development centers; and

15 “(H) ensure that the United States main-
16 tains global leadership in researching and devel-
17 oping health technologies.

18 “(d) PERSONNEL.—

19 “(1) IN GENERAL.—The Director shall establish
20 and maintain within ARPA–H a staff with appro-
21 priate qualifications and expertise to enable ARPA–
22 H to carry out the responsibilities under this section.

23 “(2) PROGRAM MANAGERS.—

24 “(A) IN GENERAL.—The Director shall
25 designate employees to serve as program man-

1 achieve designated milestones within
2 the applicable timeline;

3 “(III) the potential future com-
4 mercial applications of the project
5 proposed by the applicant;

6 “(IV) the degree to which the
7 project addresses a scientific or tech-
8 nical question pursuant to subsection
9 (c)(4)(F) and has the potential to
10 transform biomedicine, as described in
11 subsection (b); and

12 “(V) other criteria as established
13 by the Director;

14 “(v) recommend program restructure,
15 expansion, or termination of research
16 projects or whole projects, as necessary
17 and appropriate; and

18 “(vi) communicate with leaders in the
19 health care and biomedical research and
20 development fields, including from both the
21 public and private sectors, representatives
22 of patient organizations, institutions of
23 higher education, and nonprofit organiza-
24 tions, to identify areas of need and sci-
25 entific opportunity with the potential to

1 transform biomedicine as described in sub-
2 section (b).

3 “(C) TERM.—The term of a program man-
4 ager shall be not more than 3 years, and, at the
5 discretion of the Director, may be renewed for
6 one additional period of up to 3 years.

7 “(3) CONSIDERATIONS.—The Director—

8 “(A) in designating employees to serve as
9 program managers under paragraph (1), shall
10 consider, as appropriate, individuals with dem-
11 onstrated scientific expertise and management
12 skills required to advance the purposes of
13 ARPA–H, and who represent a diverse set of
14 professional experiences or backgrounds, includ-
15 ing individuals with experience in academia, in-
16 dustry, government, nonprofit organizations, or
17 other sectors; and

18 “(B) in making appointments of personnel
19 to staff or support ARPA–H, may consider
20 other factors, as appropriate, such as popu-
21 lations that are traditionally underrepresented
22 in the biomedical research enterprise.

23 “(4) HIRING.—

24 “(A) IN GENERAL.—The Director may—

1 “(i) make or rescind appointments of
2 scientific, medical, and professional per-
3 sonnel, without regard to any provision of
4 title 5, United States Code governing ap-
5 pointments under the civil service laws and
6 notwithstanding section 202 of the Depart-
7 ment of Health and Human Services Ap-
8 propriations Act, 1993 (Public Law 102–
9 394); and

10 “(ii) fix the compensation of such per-
11 sonnel at a rate to be determined by the
12 Director, up to the amount of annual com-
13 pensation (excluding expenses) specified in
14 section 102 of title 3, United States Code.

15 “(B) REPORTING.—The Director shall es-
16 tablish and maintain records regarding the use
17 of the authority under subparagraph (A)(i), in-
18 cluding—

19 “(i) the number of positions filled
20 through such authority;

21 “(ii) the types of appointments of
22 such positions;

23 “(iii) the titles, occupational series,
24 and grades of such positions;

1 “(iv) the number of positions publicly
2 noticed to be filled under such authority;

3 “(v) the number of qualified appli-
4 cants who apply for such positions;

5 “(vi) the qualification criteria for such
6 positions; and

7 “(vii) the demographic information of
8 individuals appointed to such positions.

9 “(C) REPORTS TO CONGRESS.—Not later
10 than one year after the date of enactment of
11 the PREVENT Pandemics Act, and annually
12 thereafter for each fiscal year in which such au-
13 thority is used, the Director shall submit to the
14 Committee on Health, Education, Labor, and
15 Pensions of the Senate and the Committee on
16 Energy and Commerce of the House of Rep-
17 resentatives a report describing the total num-
18 ber of appointments filled under this subsection
19 within the fiscal year and how the positions re-
20 late to the purposes of ARPA–H.

21 “(D) PRIVATE RECRUITING FIRMS.—The
22 Director may contract with private recruiting
23 firms for the hiring of qualified technical staff
24 to carry out this section.

25 “(E) CLARIFICATIONS.—

1 “(i) PREVIOUS POSITIONS.—The Di-
2 rector shall ensure that the personnel who
3 are appointed to staff or support ARPA-
4 H are individuals who, at the time of ap-
5 pointment and for 3 years prior to such
6 appointment, were not employed by the
7 National Institutes of Health.

8 “(ii) NUMBER OF PERSONNEL.—The
9 Director may appoint not more than 120
10 personnel under this section. The Director
11 shall submit a notification to Congress if
12 the Director determines that additional
13 personnel are required to carry out this
14 section.

15 “(F) GAO REPORT.—Not later than 2
16 years after the date of enactment of the PRE-
17 VENT Pandemics Act, the Comptroller General
18 of the United States shall submit to the Com-
19 mittee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on En-
21 ergy and Commerce of the House of Represent-
22 atives a report on the use of the authority pro-
23 vided under subparagraph (A)(i). Such report
24 shall, in a manner that protects personal pri-
25 vacy, to the extent required by applicable Fed-

1 eral and State privacy law, at a minimum, in-
2 clude information on—

3 “(i) the number of positions publicly
4 noticed and filled under the authority
5 under this subsection;

6 “(ii) the occupational series, grades,
7 and types of appointments of such posi-
8 tions;

9 “(iii) how such positions related to ad-
10 vancing the purposes of ARPA-H;

11 “(iv) how the Director made appoint-
12 ment decisions under this subsection;

13 “(v) sources used to identify can-
14 didates for filling such positions;

15 “(vi) the number of individuals ap-
16 pointed;

17 “(vii) aggregated demographic infor-
18 mation related to individuals appointed;
19 and

20 “(viii) any challenges, limitations, or
21 gaps related to the use of the authority
22 under this subsection and any related rec-
23 ommendations to address such challenges,
24 limitations, or gaps.

25 “(e) FUNDING AWARDS.—

1 “(1) IN GENERAL.—In carrying out this sec-
2 tion, the Director may award grants, contracts, co-
3 operative agreements, cash prizes, and enter into
4 other transactions, as described in paragraph (2).

5 “(2) OTHER TRANSACTIONS.—

6 “(A) LIMITATIONS ON ENTERING INTO
7 OTHER TRANSACTIONS.—

8 “(i) IN GENERAL.—To the maximum
9 extent practicable, competitive procedures
10 shall be used when entering into other
11 transactions to carry out projects under
12 this section.

13 “(B) WRITTEN DETERMINATIONS RE-
14 QUIRED.—The authority of this paragraph may
15 be exercised for a project if the project man-
16 ager—

17 “(i) submits a proposal to the Direc-
18 tor for each individual use of such author-
19 ity before conducting or supporting a
20 project, including why the use of such au-
21 thority is essential to promoting the suc-
22 cess of the project;

23 “(ii) receives approval for the use of
24 such authority from the Director; and

1 “(iii) for each year in which the pro-
2 gram manager has used such authority in
3 accordance with this paragraph, submits a
4 report to the Director on the activities of
5 the program relating to such project.

6 “(3) PRIZE COMPETITIONS.—The Director may
7 utilize the authorities and processes established
8 under section 24 of the Stevenson-Wydler Tech-
9 nology Innovation Act of 1980 (15 U.S.C. 3719) to
10 support prize competitions, in accordance with this
11 section.

12 “(4) FEDERAL DEMONSTRATION OF TECH-
13 NOLOGIES.—The Director may seek opportunities to
14 partner with procurement programs of Federal agen-
15 cies to demonstrate technologies resulting from ac-
16 tivities funded through ARPA–H.

17 “(5) CLARIFICATIONS.—Research supported by
18 this section shall not be subject to the requirements
19 of section 406(a)(3)(A)(ii) or 492.

20 “(f) COORDINATION, COLLABORATION, NONDUPLICA-
21 TION, AND CONSULTATION.—

22 “(1) COORDINATION.—To the maximum extent
23 practicable, the Director shall ensure that the activi-
24 ties of ARPA–H are coordinated with, and do not
25 duplicate the efforts of—

1 “(A) other programs within, or research
2 conducted or supported by, the Department of
3 Health and Human Services, including the Na-
4 tional Institutes of Health and the Biomedical
5 Advanced Research and Development Authority;
6 and

7 “(B) other relevant efforts or research and
8 development programs operated or overseen by
9 other departments, agencies, or offices of the
10 Federal Government.

11 “(2) FUNDING DETERMINATIONS.—The Direc-
12 tor shall ensure that ARPA–H does not provide
13 funding for a research program or project unless the
14 applicant for such funding demonstrates that—

15 “(A)(i) such applicant has made sufficient
16 unsuccessful attempts to secure private financ-
17 ing, and that there is a lack of significant pri-
18 vate support for the program or project; or

19 “(ii) such program or project is in the best
20 interests of the United States; and

21 “(B) such program or project has the po-
22 tential to significantly transform and advance
23 the field of biomedicine, as described in sub-
24 section (b).

1 “(3) CONSULTATION.—In carrying out this sec-
2 tion, the Director may seek input from—

3 “(A) the President’s Council of Advisors
4 on Science and Technology;

5 “(B) representatives of professional or sci-
6 entific organizations with expertise in specific
7 technologies under consideration or development
8 by ARPA–H; and

9 “(C) representatives of patient organiza-
10 tions, public health, innovators, and other pub-
11 lic and private entities.

12 “(4) ENHANCED COLLABORATION AND COMMU-
13 NICATION.—

14 “(A) IN GENERAL.—In order to facilitate
15 enhanced collaboration and communication with
16 respect to the most current priorities of ARPA–
17 H, the Food and Drug Administration may
18 meet with ARPA–H and any other appropriate
19 Federal partners, such as the Biomedical Ad-
20 vanced Research and Development Authority, at
21 appropriate intervals, to discuss the develop-
22 ment status, and actions that may be taken to
23 facilitate the development, of medical products
24 and projects that are the highest priorities to
25 ARPA–H.

1 “(B) RELATION TO OTHERWISE AUTHOR-
2 IZED ACTIVITIES OF THE FOOD AND DRUG AD-
3 MINISTRATION.—Utilizing interagency agree-
4 ments or other appropriate resource allocation
5 mechanisms available, the Director shall reim-
6 burse the Food and Drug Administration, as
7 appropriate, for activities identified by the
8 Commissioner of Food and Drugs and the Di-
9 rector as being conducted by the Food and
10 Drug Administration under the authority of
11 this section, using funds made available to
12 ARPA–H.

13 “(g) ADVISORY COMMITTEE.—

14 “(1) IN GENERAL.—There is established an
15 ARPA–H Interagency Advisory Committee (referred
16 to in this subsection as the ‘Advisory Committee’) to
17 coordinate efforts and provide advice and assistance
18 on specific program or project tasks and the overall
19 direction of ARPA–H.

20 “(2) MEMBERS.—The Advisory Committee es-
21 tablished under paragraph (1) shall consist of the
22 heads of the following agencies or their designees:

23 “(A) The National Institutes of Health.

24 “(B) The Centers for Disease Control and
25 Prevention.

1 “(C) The Food and Drug Administration.

2 “(D) The Office of the Assistant Secretary
3 for Preparedness and Response.

4 “(E) The Office of the Assistant Secretary
5 of Health.

6 “(F) The Defense Advanced Research
7 Projects Agency.

8 “(G) The Office of Science of the Depart-
9 ment of Energy.

10 “(H) The National Science Foundation.

11 “(I) Any other agency with subject matter
12 expertise that the Director of ARPA–H deter-
13 mines appropriate to advance programs or
14 projects under this section.

15 “(3) NONAPPLICABILITY OF FACA.—The Fed-
16 eral Advisory Committee Act (5 U.S.C. App.) shall
17 not apply to the Advisory Committee.

18 “(4) ADVISORY NATURE.—The functions of the
19 Advisory Committee shall be advisory in nature, and
20 nothing in this subsection shall be construed as
21 granting such Committee authority over the activi-
22 ties authorized under this section.

23 “(5) PERFORMANCE MEASURES FRAMEWORK.—
24 The Director, in consultation with the Advisory
25 Committee, shall develop a performance measures

1 framework for programs or projects supported by
2 ARPA–H in order to inform and facilitate the eval-
3 uation required under subsection (m), including
4 identification of any data needed to perform such
5 evaluation, consistent with subsection (l).

6 “(h) FACILITIES.—

7 “(1) AUTHORITIES.—The Director is author-
8 ized to—

9 “(A) acquire (by purchase, lease, con-
10 demnation or otherwise), construct, improve, re-
11 pair, operate, and maintain such real and per-
12 sonal property as are necessary to carry out
13 this section; and

14 “(B) lease an interest in property for not
15 more than 20 years, notwithstanding section
16 1341(a)(1) of title 31, United States Code.

17 “(2) LOCATIONS.—

18 “(A) IN GENERAL.—ARPA–H, including
19 its headquarters, shall not be located, including
20 headquartered, inside of, or in close proximity
21 to, the National Capital region, and shall not be
22 located on any part of the National Institutes
23 of Health campuses.

24 “(B) CONSIDERATIONS.—In determining
25 the location of facilities, the Director shall con-

1 sider the characteristics of the intended location
2 and the extent to which such location will facili-
3 tate advancement of the ARPA–H purposes
4 pursuant to subsection (b).

5 “(i) RULE OF CONSTRUCTION.—The authorities
6 granted by this section—

7 “(1) are in addition to existing authorities
8 granted to the Secretary; and

9 “(2) shall not be construed to modify or super-
10 sede any existing authorities.

11 “(j) PROTECTION OF INFORMATION.—

12 “(1) IN GENERAL.—Nothing in this section
13 shall be construed as authorizing the Secretary to
14 disclose any information that is a trade secret, or
15 other privileged or confidential information subject
16 to section 552(b)(4) of title 5, United States Code,
17 or section 1905 of title 18, United States Code.

18 “(2) REPORTING.—One year after the date of
19 enactment of the PREVENT Pandemics Act, and
20 annually thereafter, the Director shall report to the
21 Committee on Health, Education, Labor, and Pen-
22 sions of the Senate and the Committee on Energy
23 and Commerce of the House of Representatives on—

24 “(A) the number of instances in which the
25 Secretary has used the authority under this

1 subsection to withhold information from disclo-
2 sure; and

3 “(B) the nature of any request under sec-
4 tion 552 of title 5, United States Code, or sec-
5 tion 1905 of title 18, United States Code, that
6 was denied using such authority.

7 “(k) REPORTS AND STRATEGIC PLANS.—

8 “(1) ANNUAL REPORT.—As part of the annual
9 budget request submitted for each fiscal year, the
10 Director shall provide to the Committee on Health,
11 Education, Labor, and Pensions and the Committee
12 on Appropriations of the Senate and the Committee
13 on Energy and Commerce and the Committee on
14 Appropriations of the House of Representatives a re-
15 port that describes—

16 “(A) projects supported by ARPA–H dur-
17 ing the previous fiscal year, and, with respect to
18 each such project, the stage of development and
19 details as to whether the project is meeting
20 project milestones;

21 “(B) projects supported by ARPA–H in
22 the previous fiscal year that were terminated,
23 and the reasons for termination;

24 “(C) projects supported by ARPA–H dur-
25 ing the previous fiscal year that examine topics

1 and technologies closely related to other activi-
2 ties funded by the Department of Health and
3 Human Services, including an analysis of
4 whether in supporting such projects, the Direc-
5 tor is in compliance with the requirements of
6 this section; and

7 “(D) current, proposed, and planned
8 projects to be carried out.

9 “(2) STRATEGIC PLAN.—Not later than 180
10 days after the appointment of the first Director pur-
11 suant to subsection (c), and every 4 years thereafter,
12 the Director shall provide to the Committee on
13 Health, Education, Labor, and Pensions and the
14 Committee on Appropriations of the Senate and the
15 Committee on Energy and Commerce and the Com-
16 mittee on Appropriations of the House of Represent-
17 atives a plan describing the strategic plan that
18 ARPA–H will use to guide future investments over
19 the following 4 fiscal years. Every 2 years after the
20 date of submission of the initial plan, the Director
21 shall submit a supplemental strategic plan that de-
22 tails any changes to such strategic vision, as appro-
23 priate. The requirements regarding individual insti-
24 tute and center strategic plans under section

1 402(m), including paragraph (3) of such subsection,
2 shall not apply to ARPA–H.

3 “(l) NATIONAL ACADEMIES OF SCIENCES, ENGI-
4 NEERING, AND MEDICINE EVALUATION.—

5 “(1) IN GENERAL.—Not later than 3 years
6 after the date of enactment of the PREVENT
7 Pandemics Act, the Director shall seek to enter into
8 a contract with the National Academies of Sciences,
9 Engineering, and Medicine under which the National
10 Academies conducts an evaluation of ARPA–H re-
11 garding the goals and purposes of ARPA–H and the
12 degree to which the activities of ARPA–H support,
13 and align with, such goals and purposes.

14 “(2) INCLUSIONS.—The evaluation under para-
15 graph (1) may include—

16 “(A) recommendations on how to improve
17 upon the operation of, and projects carried out
18 by, ARPA–H, which may include lessons
19 learned from other advanced research and de-
20 velopment agencies or authorities within the
21 Department of Health and Human Services and
22 in other departments, agencies, or offices of the
23 Federal Government;

24 “(B) a description of lessons learned from
25 the establishment and operation of ARPA–H,

1 and the manner in which those lessons may
2 apply to the operation of other programs of the
3 Department of Health and Human Services;
4 and

5 “(C) an analysis of whether any projects
6 supported by ARPA–H were duplicative of
7 other research programs supported by the De-
8 partment of Health and Human Services or
9 other another relevant Federal department or
10 agency.

11 “(3) AVAILABILITY.—Upon completion of the
12 evaluation, the evaluation shall be submitted by the
13 Director to the Committee on Health, Education,
14 Labor, and Pensions and the Committee on Appro-
15 priations of the Senate and the Committee on En-
16 ergy and Commerce and the Committee on Appro-
17 priations of the House of Representatives and made
18 publicly available.

19 “(m) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there are authorized to be appro-
21 priated such sums as may be necessary for each of fiscal
22 years 2023 through 2027.

23 “(n) ADDITIONAL BUDGET CLARIFICATION.—Any
24 budget request for ARPA–H shall be separate from the

1 other budget requests of the National Institutes of
2 Health.”.

3 **TITLE IV—MODERNIZING AND**
4 **STRENGTHENING THE SUP-**
5 **PLY CHAIN FOR VITAL MED-**
6 **ICAL PRODUCTS**

7 **SEC. 401. WARM BASE MANUFACTURING CAPACITY FOR**
8 **MEDICAL COUNTERMEASURES.**

9 (a) IN GENERAL.—Section 319L of the Public
10 Health Service Act (42 U.S.C. 247d–7e) is amended—

11 (1) in subsection (a)(6)(B)—

12 (A) by redesignating clauses (iv) and (v) as
13 clauses (v) and (vi), respectively;

14 (B) by inserting after clause (iii), the fol-
15 lowing:

16 “(iv) activities to support, maintain,
17 and improve domestic manufacturing surge
18 capacity and capabilities, as appropriate,
19 including through the utilization of ad-
20 vanced manufacturing and platform tech-
21 nologies, to increase the availability of
22 products that are or may become qualified
23 countermeasures or qualified pandemic or
24 epidemic products;”; and

1 (C) in clause (vi) (as so redesignated), by
2 inserting “manufacturing,” after “improve-
3 ment,”;

4 (2) in subsection (b)—

5 (A) in the first sentence of paragraph (1),
6 by inserting “support for domestic manufac-
7 turing surge capacity and capabilities,” after
8 “initiatives for innovation,”; and

9 (B) in paragraph (2)—

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

12 (ii) by redesignating subparagraph
13 (C) as subparagraph (D); and

14 (iii) by inserting after subparagraph
15 (B), the following:

16 “(C) activities to support, maintain, and
17 improve domestic manufacturing surge capacity
18 and capabilities, as appropriate, including
19 through the utilization of advanced manufac-
20 turing and platform technologies, to increase
21 the availability of products that are or may be-
22 come qualified countermeasures or qualified
23 pandemic or epidemic products; and”;

24 (3) in subsection (c)—

1 (A) in paragraph (2)(B), by inserting be-
2 fore the semicolon “, including through the es-
3 tablishment and maintenance of domestic man-
4 ufacturing surge capacity and capabilities, con-
5 sistent with subsection (a)(6)(B)(iv)”;

6 (B) in paragraph (4)—

7 (i) in subparagraph (A)—

8 (I) in clause (i)—

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

11 (bb) by adding at the end
12 the following:

13 “(III) facilitating such commu-
14 nication, as appropriate, regarding
15 manufacturing surge capacity and ca-
16 pabilities with respect to qualified
17 countermeasures and qualified pan-
18 demic or epidemic products to prepare
19 for, or respond to, a public health
20 emergency or potential public health
21 emergency; and

22 “(IV) facilitating such commu-
23 nication, as appropriate and in a man-
24 ner that does not compromise national
25 security, with respect to potential eli-

1 gibility for the material threat medical
2 countermeasure priority review vouch-
3 er program under section 565A of the
4 Federal Food, Drug, and Cosmetic
5 Act;”;

6 (II) in clause (ii)(III), by striking
7 “and” at the end;

8 (III) by redesignating clause (iii)
9 as clause (iv); and

10 (IV) by inserting after clause (ii),
11 the following:

12 “(iii) communicate regularly with enti-
13 ties in receipt of an award pursuant to
14 subparagraph (B)(v), and facilitate com-
15 munication between such entities and other
16 entities in receipt of an award pursuant to
17 subparagraph (B)(iv), as appropriate, for
18 purposes of planning and response regard-
19 ing the availability of countermeasures and
20 the maintenance of domestic manufac-
21 turing surge capacity and capabilities, in-
22 cluding any planned uses of such capacity
23 and capabilities in the near- and mid-term,
24 and identification of any significant chal-
25 lenges related to the long-term mainte-

1 nance of such capacity and capabilities;
2 and”;

3 (ii) in subparagraph (B)—

4 (I) in clause (iii), by striking
5 “and” at the end;

6 (II) in clause (iv), by striking the
7 period and inserting “; and”; and

8 (III) by adding at the end the
9 following:

10 “(v) award contracts, grants, and co-
11 operative agreements and enter into other
12 transactions to support, maintain, and im-
13 prove domestic manufacturing surge capac-
14 ity and capabilities, including through sup-
15 porting flexible or advanced manufac-
16 turing, to ensure that additional capacity
17 is available to rapidly manufacture prod-
18 ucts that are or may become qualified
19 countermeasures or qualified pandemic or
20 epidemic products in the event of a public
21 health emergency declaration or significant
22 potential for a public health emergency.”;

23 (iii) in subparagraph (C)—

24 (I) in clause (i), by striking
25 “and” at the end;

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

4 (III) by adding at the end the
5 following:

6 “(iii) consult with the Commissioner
7 of Food and Drugs, pursuant to section
8 565(b)(2) of the Federal Food, Drug, and
9 Cosmetic Act, to ensure that facilities per-
10 forming manufacturing, pursuant to an
11 award under subparagraph (B)(v), are in
12 compliance with applicable requirements
13 under such Act and this Act, as appro-
14 priate, including current good manufac-
15 turing practice pursuant to section
16 501(a)(2)(B) of the Food, Drug, and Cos-
17 metic Act; and”;

18 (iv) in subparagraph (D)(i), by insert-
19 ing “, including to improve manufacturing
20 capacities and capabilities for medical
21 countermeasures” before the semicolon;

22 (v) in subparagraph (E)(ix), by strik-
23 ing “2023” and inserting “2028”; and

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

1 “(G) ANNUAL REPORTS BY AWARD RECIPI-
2 ENTS.—As a condition of receiving an award
3 under subparagraph (B)(v), a recipient shall de-
4 velop and submit to the Secretary annual re-
5 ports related to the maintenance of such capac-
6 ity and capabilities, including ensuring that
7 such capacity and capabilities are able to sup-
8 port the rapid manufacture of countermeasures
9 as required by the Secretary.”; and

10 (C) in paragraph (5), by adding at the end
11 the following:

12 “(H) SUPPORTING WARM-BASE AND SURGE
13 CAPACITY AND CAPABILITIES.—Pursuant to an
14 award under subparagraph (B)(v), the Sec-
15 retary may make payments for activities nec-
16 essary to maintain domestic manufacturing
17 surge capacity and capabilities supported under
18 such award to ensure that such capacity and
19 capabilities are able to support the rapid manu-
20 facture of countermeasures as required by the
21 Secretary to prepare for, or respond to, an ex-
22 isting or potential public health emergency or
23 otherwise address threats that pose a signifi-
24 cant level of risk to national security. The Sec-
25 retary may support the utilization of such ca-

1 capacity and capabilities under awards for coun-
2 termeasure and product advanced research and
3 development, as appropriate, to provide for the
4 maintenance of such capacity and capabilities.”;
5 and

6 (4) in subsection (f)—

7 (A) in paragraph (1), by striking “Not
8 later than 180 days after the date of enactment
9 of this subsection” and inserting “Not later
10 than 180 days after the date of enactment of
11 the PREVENT Pandemics Act”;

12 (B) in paragraph (2)—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “this subsection”
15 and inserting “the PREVENT Pandemics
16 Act”;

17 (ii) in subparagraph (B), by striking
18 “and” at the end; and

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

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

22 “(D) plans for the near-, mid-, and long-
23 term sustainment of manufacturing activities
24 carried out under this section, including such
25 activities pursuant to subsection (c)(5)(H), spe-

1 products, including information
2 on supply chain redundancies,
3 any known domestic manufac-
4 turing capacity for such prod-
5 ucts, and any related
6 vulnerabilities;”.

7 **SEC. 403. STRATEGIC NATIONAL STOCKPILE EQUIPMENT**
8 **MAINTENANCE.**

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

11 (1) in subparagraph (B), by inserting “, regu-
12 larly reviewed, and updated” after “followed”; and

13 (2) by amending subparagraph (D) to read as
14 follows:

15 “(D) review and revise, as appropriate, the
16 contents of the stockpile on a regular basis to
17 ensure that—

18 “(i) emerging threats, advanced tech-
19 nologies, and new countermeasures are
20 adequately considered;

21 “(ii) the potential depletion of coun-
22 termeasures currently in the stockpile is
23 identified and appropriately addressed, in-
24 cluding through necessary replenishment;
25 and

1 “(iii) such contents are in working
2 condition or usable, as applicable, and are
3 ready for deployment, which may include
4 conducting maintenance services on such
5 contents of the stockpile and disposing of
6 such contents that are no longer in work-
7 ing condition, or usable, as applicable;”.

8 **SEC. 404. IMPROVING TRANSPARENCY AND PREDICT-**
9 **ABILITY OF PROCESSES OF THE STRATEGIC**
10 **NATIONAL STOCKPILE.**

11 (a) GUIDANCE.—Not later than 60 days after the
12 date of enactment of this Act, the Secretary of Health and
13 Human Services (referred to in this section as the “Sec-
14 retary”) shall issue guidance describing the processes by
15 which the Secretary deploys the contents of the Strategic
16 National Stockpile under section 319F-2(a) of the Public
17 Health Service Act (42 U.S.C. 247d-6b(a)), or otherwise
18 distributes medical countermeasures, as applicable, to
19 States, territories, Indian Tribes and Tribal organizations
20 (as such terms are defined under section 4 of the Indian
21 Self-Determination and Education Assistance Act), and
22 other applicable entities. Such guidance shall include in-
23 formation related to processes by which to request access
24 to the contents of the Strategic National Stockpile, factors
25 considered by the Secretary when making deployment or

1 distribution decisions, and processes and points of contact
2 through which entities may contact the Secretary to ad-
3 dress any issues related to products requested or received
4 by such entity from the stockpile, and on other relevant
5 topics.

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

9 (1) in subparagraph (I), by striking “and” at
10 the end;

11 (2) in subparagraph (J), by striking the period
12 at the end and inserting “; and”; and

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

14 “(K) convene meetings, not less than once
15 per year, with representatives from State, local,
16 and Tribal health departments or officials, rel-
17 evant industries, other Federal agencies, and
18 other appropriate stakeholders, in a manner
19 that does not compromise national security, to
20 coordinate and share information related to
21 maintenance and use of the stockpile, including
22 a description of future countermeasure needs
23 and additions, modifications, and replenish-
24 ments of the contents of the stockpile, and con-
25 siderations related to the manufacturing and

1 procurement of products consistent with the re-
2 quirements of the Buy American Act of 1933,
3 as appropriate.”.

4 **SEC. 405. IMPROVING SUPPLY CHAIN FLEXIBILITY FOR THE**
5 **STRATEGIC NATIONAL STOCKPILE.**

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

8 (1) in subsection (a)—

9 (A) in paragraph (3)(F), by striking “as
10 required by the Secretary of Homeland Secu-
11 rity” and inserting “at the discretion of the
12 Secretary, in consultation with, or at the re-
13 quest of, the Secretary of Homeland Security,”;

14 (B) by redesignating paragraphs (5) and
15 (6) as paragraphs (6) and (7), respectively;

16 (C) by inserting after paragraph (4) the
17 following:

18 “(5) VENDOR-MANAGED INVENTORY AND
19 WARM-BASE SURGE CAPACITY.—

20 “(A) IN GENERAL.—For the purposes of
21 maintaining the stockpile under paragraph (1)
22 and carrying out procedures under paragraph
23 (3), the Secretary may enter into contracts or
24 cooperative agreements with vendors, which
25 may include manufacturers or distributors of

1 medical products, with respect to medical prod-
2 ucts intended to be delivered to the ownership
3 of the Federal Government. Each such contract
4 or cooperative agreement shall be subject to
5 such terms and conditions as the Secretary may
6 specify, including terms and conditions with re-
7 spect to—

8 “(i) procurement, maintenance, stor-
9 age, and delivery of products, in alignment
10 with inventory management and other ap-
11 plicable best practices, under such contract
12 or cooperative agreement, which may con-
13 sider, as appropriate, costs of transporting
14 and handling such products; or

15 “(ii) maintenance of domestic manu-
16 facturing capacity and capabilities of such
17 products to ensure additional reserved pro-
18 duction capacity and capabilities are avail-
19 able, and that such capacity and capabili-
20 ties are able to support the rapid manufac-
21 ture, purchase, storage, and delivery of
22 such products, as required by the Sec-
23 retary to prepare for, or respond to, an ex-
24 isting or potential public health emergency.

1 “(B) 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 any con-
10 tracts or cooperative agreements entered into
11 under subparagraph (A) for purposes of estab-
12 lishing and maintaining vendor-managed inven-
13 tory or reserve manufacturing capacity and ca-
14 pabilities for products intended for the stock-
15 pile, including a description of—

16 “(i) the amount of each award;

17 “(ii) the recipient of each award;

18 “(iii) the product or products covered
19 through each award; and

20 “(iv) how the Secretary works with
21 each recipient to ensure situational aware-
22 ness related to the manufacturing capacity
23 for, or inventory of, such products and co-
24 ordinates the distribution and deployment

1 of such products, as appropriate and appli-
2 cable.”; and

3 (D) in subparagraph (A) of paragraph (6),
4 as so redesignated—

5 (i) in clause (viii), by striking “; and”
6 and inserting a semicolon;

7 (ii) in clause (ix), by striking the pe-
8 riod and inserting “; and”; and

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

11 “(x) with respect to reports issued in
12 2027 or any subsequent year, an assess-
13 ment of selected contracts or cooperative
14 agreements entered into pursuant to para-
15 graph (5).”; and

16 (2) in subsection (c)(2)(C), by striking “on an
17 annual basis” and inserting “not later than March
18 15 of each year”.

19 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
20 319F–2(f)(1) of the Public Health Service Act (42 U.S.C.
21 247d–6b(f)(1)) is amended by striking “\$610,000,000 for
22 each of fiscal years 2019 through 2023” and inserting
23 “\$610,000,000 for each of fiscal year 2019 through 2021,
24 and \$750,000,000 for each of fiscal years 2022 and
25 2023”.

1 **SEC. 406. REIMBURSEMENT FOR CERTAIN SUPPLIES.**

2 Paragraph (7) of section 319F–2(a) of the Public
3 Health Service Act (42 U.S.C. 247d–6b(a)), as so redesi-
4 gnated by section 405(a)(1)(B), is amended to read as fol-
5 lows:

6 “(7) REIMBURSEMENT FOR CERTAIN SUP-
7 PLIES.—

8 “(A) IN GENERAL.—The Secretary may, at
9 appropriate intervals, make available for pur-
10 chase excess contents procured for, and main-
11 tained within, the stockpile under paragraph (1)
12 to any Federal agency or State, local, or Tribal
13 government. The Secretary shall make such
14 contents available for purchase only if—

15 “(i) such contents are in excess of
16 what is required for appropriate mainte-
17 nance of such stockpile;

18 “(ii) the Secretary determines that
19 the costs for maintaining such excess con-
20 tents are not appropriate to expend to
21 meet the needs of the stockpile; and

22 “(iii) the Secretary determines that
23 such action does not compromise national
24 security and is in the national interest.

25 “(B) REIMBURSEMENT AND COLLEC-
26 TION.—The Secretary may require reimburse-

1 ment for contents that are made available
2 under subparagraph (A), in an amount that re-
3 flects the cost of acquiring and maintaining
4 such contents and the costs incurred to make
5 available such contents in the time and manner
6 specified by the Secretary. Amounts collected
7 under this subsection shall be credited to the
8 appropriations account or fund that incurred
9 the costs to procure such contents, and shall re-
10 main available, without further appropriation,
11 until expended, for the purposes of the appro-
12 priation account or fund so credited.

13 “(C) RULE OF CONSTRUCTION.—This
14 paragraph shall not be construed to preclude
15 transfers of contents in the stockpile under
16 other authorities.

17 “(D) REPORT.—Not later than 2 years
18 after the date of enactment of the PREVENT
19 Pandemics Act, and annually thereafter, the
20 Secretary shall submit to the Committee on
21 Health, Education, Labor, and Pensions and
22 the Committee on Appropriations of the Senate
23 and the Committee on Energy and Commerce
24 and the Committee on Appropriations of the
25 House of Representatives a report on the use of

1 the authority provided under this paragraph, in-
2 cluding details of each action taken pursuant to
3 this paragraph, the account or fund to which
4 any collected amounts have been credited, and
5 how the Secretary has used such amounts.

6 “(E) SUNSET.—The authority under this
7 paragraph shall terminate on September 30,
8 2028.”.

9 **SEC. 407. ACTION REPORTING ON STOCKPILE DEPLETION.**

10 Section 319 of the Public Health Service Act (42
11 U.S.C. 247d), as amended by section 223, is further
12 amended by adding at the end the following:

13 “(h) STOCKPILE DEPLETION REPORTING.—The Sec-
14 retary shall, not later than 30 days after the deployment
15 of contents of the Strategic National Stockpile under sec-
16 tion 319F–2(a) to respond to a public health emergency
17 declared by the Secretary under this section or an emer-
18 gency or major disaster declared by the President under
19 the Robert T. Stafford Disaster Relief and Emergency As-
20 sistance Act, and every 30 days thereafter until the expira-
21 tion or termination of such public health emergency, emer-
22 gency, or major disaster, submit a report to the Com-
23 mittee on Health, Education, Labor, and Pensions and the
24 Committee on Appropriations of the Senate and the Com-

1 mittee on Energy and Commerce and the Committee on
2 Appropriations of the House of Representatives on—

3 “(1) the deployment of the contents of the
4 stockpile in response to State, local, and Tribal re-
5 quests;

6 “(2) the amount of such products that remain
7 within the stockpile following such deployment; and

8 “(3) plans to replenish such products, as appro-
9 priate, including related timeframes and any barriers
10 or limitations to replenishment.”.

11 **SEC. 408. PROVISION OF MEDICAL COUNTERMEASURES TO**
12 **INDIAN PROGRAMS AND FACILITIES.**

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

16 (1) in subparagraph (C), by striking “and
17 local” and inserting “local, and Tribal”; and

18 (2) in subparagraph (J), by striking “and
19 local” and inserting “local, and Tribal”.

20 (b) DISTRIBUTION OF MEDICAL COUNTERMEASURES
21 TO INDIAN TRIBES.—Title III of the Public Health Serv-
22 ice Act (42 U.S.C. 241 et seq.) is amended by inserting
23 after section 319F–4 the following:

1 **“SEC. 319F-5. PROVISION OF MEDICAL COUNTERMEASURES**
2 **TO INDIAN PROGRAMS AND FACILITIES.**

3 “In the event that the Secretary deploys the contents
4 of the Strategic National Stockpile under section 319F–
5 2(a), or otherwise distributes medical countermeasures to
6 States to respond to a public health emergency declared
7 by the Secretary under section 319, the Secretary shall,
8 in consultation with the applicable States, make such con-
9 tents or countermeasures directly available to Indian
10 Tribes and Tribal organizations (as such terms are de-
11 fined in section 4 of the Indian Self-Determination and
12 Education Assistance Act (25 U.S.C. 5304), which may
13 include through health programs or facilities operated by
14 the Indian Health Service, that are affected by such public
15 health emergency.”.

16 **SEC. 409. GRANTS FOR STATE STRATEGIC STOCKPILES.**

17 (a) Section 319F–2 of the Public Health Service Act
18 (42 U.S.C. 247d–6b) is amended by adding at the end
19 the following:

20 “(i) **PILOT PROGRAM TO SUPPORT STATE MEDICAL**
21 **STOCKPILES.—**

22 “(1) **IN GENERAL.—**The Secretary, in consulta-
23 tion with the Assistant Secretary for Preparedness
24 and Response and the Director of the Centers for
25 Disease Control and Prevention, shall award grants
26 or cooperative agreements to not fewer than 5

1 States, or consortia of States, with consideration
2 given to distribution among the geographical regions
3 of the United States, to establish, expand, or main-
4 tain a stockpile of appropriate drugs, vaccines and
5 other biological products, medical devices, and other
6 medical supplies determined by the State to be nec-
7 essary to respond to a public health emergency de-
8 clared by the Governor of a State or by the Sec-
9 retary under section 319, or a major disaster or
10 emergency declared by the President under section
11 401 or 501, respectively, of the Robert T. Stafford
12 Disaster Relief and Emergency Assistance Act, in
13 order to support the preparedness goals described in
14 paragraphs (2) through (6) and (8) of section
15 2802(b).

16 “(2) REQUIREMENTS.—

17 “(A) APPLICATION.—To be eligible to re-
18 ceive an award under paragraph (1), an entity
19 shall prepare, in consultation with appropriate
20 health care entities and health officials within
21 the jurisdiction of such State or States, and
22 submit to the Secretary an application that con-
23 tains such information as the Secretary may re-
24 quire, including—

1 subsection unless the applicant agrees,
2 with respect to the costs to be incurred by
3 the applicant in carrying out the purpose
4 described in this subsection, to make avail-
5 able non-Federal contributions toward such
6 costs in an amount equal to—

7 “(I) for each of fiscal years 2023
8 and 2024, not less than \$1 for each
9 \$20 of Federal funds provided in the
10 award; and

11 “(II) for fiscal year 2025 and
12 each fiscal year thereafter, not less
13 than \$1 for each \$10 of Federal funds
14 provided in the award.

15 “(ii) WAIVER.—The Secretary may,
16 upon the request of a State, waive the re-
17 quirement under clause (i), in whole or in
18 part, if the Secretary determines that ex-
19 traordinary economic conditions in the
20 State in the fiscal year involved or in the
21 previous fiscal year justify the waiver. A
22 waiver provided by the Secretary under
23 this subparagraph shall apply only to the
24 fiscal year involved.

1 “(C) ADMINISTRATIVE EXPENSES.—Not
2 more than 10 percent of amounts received by
3 an entity pursuant to an award under this sub-
4 section may be used for administrative ex-
5 penses.

6 “(3) LEAD ENTITY.—An entity in receipt of an
7 award under paragraph (1) may designate a lead en-
8 tity, which may be a public or private entity, as ap-
9 propriate, to manage the stockpile at the direction of
10 the State or consortium of States.

11 “(4) USE OF FUNDS.—An entity in receipt of
12 an award under paragraph (1) shall use such funds
13 to—

14 “(A) purchase, store, and maintain a
15 stockpile of appropriate drugs, vaccines and
16 other biological products, medical devices, and
17 other medical supplies to be used during a pub-
18 lic health emergency, major disaster, or emer-
19 gency described in paragraph (1), in such num-
20 bers, types, and amounts as the entity deter-
21 mines necessary, consistent with such entity’s
22 stockpile plan established pursuant to para-
23 graph (2)(A)(i);

24 “(B) deploy the stockpile as required by
25 the entity to respond to an actual or potential

1 public health emergency, major disaster, or
2 other emergency described in paragraph (1);

3 “(C) replenish and make necessary addi-
4 tions or modifications to the contents of such
5 stockpile, including to address potential deple-
6 tion;

7 “(D) in consultation with Federal, State,
8 and local officials, take into consideration the
9 availability, deployment, dispensing, and admin-
10 istration requirements of medical products with-
11 in the stockpile;

12 “(E) ensure that procedures are followed
13 for inventory management and accounting, and
14 for the physical security of the stockpile, as ap-
15 propriate;

16 “(F) review and revise, as appropriate, the
17 contents of the stockpile on a regular basis to
18 ensure that, to the extent practicable, new tech-
19 nologies and medical products are considered;

20 “(G) carry out exercises, drills, and other
21 training for purposes of stockpile deployment,
22 dispensing, and administration of medical prod-
23 ucts, and for purposes of assessing the capa-
24 bility of such stockpile to address the medical
25 supply needs of public health emergencies,

1 major disasters, or other emergencies described
2 in paragraph (1) of varying types and scales,
3 which may be conducted in accordance with re-
4 quirements related to exercises, drills, and other
5 training for recipients of awards under section
6 319C–1 or 319C–2, as applicable; and

7 “(H) carry out other activities related to
8 the State strategic stockpile as the entity deter-
9 mines appropriate, to support State efforts to
10 prepare for, and respond to, public health
11 threats.

12 “(5) SUPPLEMENT NOT SUPPLANT.—Awards
13 under paragraph (1) shall supplement, not supplant,
14 the maintenance and use of the Strategic National
15 Stockpile by the Secretary under subsection (a).

16 “(6) GUIDANCE FOR STATES.—Not later than
17 180 days after the date of enactment of this sub-
18 section, the Secretary, in consultation with States,
19 health officials, and other relevant stakeholders, as
20 appropriate, shall issue guidance, and update such
21 guidance as appropriate, for States related to main-
22 taining and replenishing a stockpile of medical prod-
23 ucts, which may include strategies and best practices
24 related to—

1 “(A) types of medical products and med-
2 ical supplies that are critical to respond to pub-
3 lic health emergencies, and may be appropriate
4 for inclusion in a stockpile by States, with con-
5 sideration of threats that require the large-scale
6 and simultaneous deployment of stockpiles, in-
7 cluding the stockpile maintained by the Sec-
8 retary pursuant to subsection (a), and long-
9 term public health and medical response needs;

10 “(B) appropriate management of the con-
11 tents of a stockpile, including management by
12 vendors of reserve amounts of medical products
13 and supplies intended to be delivered to the
14 ownership of the State and appropriate disposi-
15 tion of excess products, as applicable; and

16 “(C) the procurement of medical products
17 and medical supplies consistent with the re-
18 quirements of chapter 83 of title 41, United
19 States Code (commonly referred to as the ‘Buy
20 American Act’).

21 “(7) TECHNICAL ASSISTANCE.—The Secretary
22 shall provide assistance to States, including technical
23 assistance, as appropriate, in establishing, maintain-
24 ing, improving, and utilizing a medical stockpile, in-

1 including appropriate inventory management and dis-
2 position of products.

3 “(8) REPORTING.—

4 “(A) STATE REPORTS.—Each entity re-
5 ceiving an award under paragraph (1) shall up-
6 date, as appropriate, the plan established pur-
7 suant to paragraph (2)(A)(i) and submit to the
8 Secretary an annual report on implementation
9 of such plan, including any changes to the con-
10 tents of the stockpile supported under such
11 award. The Secretary shall use information ob-
12 tained from such reports to inform the mainte-
13 nance and management of the Strategic Na-
14 tional Stockpile pursuant to subsection (a).

15 “(B) REPORTS TO CONGRESS.—Not later
16 than 1 year after the initial issuance of awards
17 pursuant to paragraph (1), and annually there-
18 after for the duration of the program estab-
19 lished under this subsection, the Secretary shall
20 submit to the Committee on Health, Education,
21 Labor, and Pensions and the Committee on Ap-
22 propriations of the Senate and the Committee
23 on Energy and Commerce and the Committee
24 on Appropriations of the House of Representa-
25 tives a report on such program, including—

1 (2) technical assistance provided by the Sec-
2 retary of Health and Human Services to such enti-
3 ties; and

4 (3) the impact of such stockpiles on the ability
5 of the State to prepare for and respond to a public
6 health emergency, major disaster, or other emer-
7 gency described in subsection (i)(1) of section 319F-
8 2 of the Public Health Service Act (42 U.S.C. 247d-
9 6b), as added by subsection (a), including the avail-
10 ability and distribution of items from such State
11 stockpile to health care entities and other applicable
12 entities.

13 **SEC. 410. STUDY ON INCENTIVES FOR DOMESTIC PRODUC-**
14 **TION OF GENERIC MEDICINES.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services (referred to in this section as the “Sec-
17 retary”), acting through the Assistant Secretary for Plan-
18 ning and Evaluation of the Department of Health and
19 Human Services shall—

20 (1) conduct a study on the feasibility, including
21 related to sustainment, and potential effectiveness,
22 and utility of providing incentives for increased do-
23 mestic production and capacity of specified generic
24 medicines and their active pharmaceutical ingredi-
25 ents; and

1 (2) not later than 1 year after the date of en-
2 actment of this Act, submit a report on such study
3 to the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Committee on En-
5 ergy and Commerce of the House of Representa-
6 tives.

7 (b) SPECIFIED GENERIC MEDICINE.—In this section,
8 the term “specified generic medicine” means a generic
9 drug approved under section 505(j) of the Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355(j)) that is —

11 (1) used to prevent, mitigate, or treat a serious
12 or life-threatening disease or condition, or used in a
13 common procedure that could be life-threatening
14 without such medicine;

15 (2) an antibiotic or antifungal used to treat a
16 serious or life threatening infectious disease;

17 (3) critical to the public health during a public
18 health emergency; or

19 (4) life-supporting, life-sustaining, or intended
20 for use in the prevention or treatment of a debili-
21 tating disease or condition.

1 **TITLE V—ENHANCING DEVELOP-**
2 **MENT AND COMBATING**
3 **SHORTAGES OF MEDICAL**
4 **PRODUCTS**

5 **Subtitle A—Development and**
6 **Review**

7 **SEC. 501. ADVANCING QUALIFIED INFECTIOUS DISEASE**
8 **PRODUCT INNOVATION.**

9 (a) IN GENERAL.—Section 505E of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amend-
11 ed—

12 (1) in subsection (c)—

13 (A) in paragraph (2), by striking “; or”
14 and inserting “;”;

15 (B) in paragraph (3), by striking the pe-
16 riod and inserting “; or”; and

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

18 “(4) an application pursuant to section 351(a)
19 of the Public Health Service Act.”;

20 (2) in subsection (d)(1), by inserting “of this
21 Act or section 351(a) of the Public Health Service
22 Act” after “section 505(b)”; and

23 (3) by amending subsection (g) to read as fol-
24 lows:

1 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—

2 The term ‘qualified infectious disease product’ means a
3 drug (including a biological product), including an anti-
4 bacterial or antifungal drug, for human use that—

5 “(1) acts directly on bacteria or fungi or on
6 substances produced by such bacteria or fungi; and

7 “(2) is intended to treat a serious or life-threat-
8 ening infection, including such an infection caused
9 by—

10 “(A) an antibacterial or antifungal resist-
11 ant pathogen, including novel or emerging in-
12 fectious pathogens; or

13 “(B) qualifying pathogens listed by the
14 Secretary under subsection (f).”.

15 (b) PRIORITY REVIEW.—Section 524A(a) of the Fed-
16 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a))
17 is amended by inserting “of this Act, or section 351(a)
18 of the Public Health Service Act, that requires clinical
19 data (other than bioavailability studies) to demonstrate
20 safety or effectiveness” before the period.

21 **SEC. 502. MODERNIZING CLINICAL TRIALS.**

22 (a) CLARIFYING THE USE OF DIGITAL HEALTH
23 TECHNOLOGIES IN CLINICAL TRIALS.—

24 (1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this Act, the Secretary of

1 Health and Human Services (referred to in this sec-
2 tion as the “Secretary”) shall issue or revise draft
3 guidance regarding the appropriate use of validated
4 digital health technologies in clinical trials to help
5 improve recruitment for, retention in, participation
6 in, and data collection during, clinical trials, and
7 provide for novel clinical trial designs utilizing such
8 technology for purposes of supporting the develop-
9 ment of, and review of applications for, drugs and
10 devices. Not later than 18 months after the public
11 comment period on such draft guidance ends, the
12 Secretary shall issue a revised draft guidance or
13 final guidance.

14 (2) CONTENT.—The guidance described in
15 paragraph (1) shall include—

16 (A) recommendations for data collection
17 methodologies by which sponsors may incor-
18 porate the use of digital health technologies in
19 clinical trials to collect data remotely from trial
20 participants;

21 (B) considerations for privacy and security
22 protections for data collected during a clinical
23 trial, including—

24 (i) recommendations for the protec-
25 tion of trial participant data that is col-

1 lected or used in research, using digital
2 health technologies;

3 (ii) compliance with the regulations
4 promulgated under section 264(c) of the
5 Health Insurance Portability and Account-
6 ability Act of 1996 (42 U.S.C. 1320d-2
7 note), subpart B of part 50 of title 21,
8 Code of Federal Regulations, subpart C of
9 part 56 of title 21, Code of Federal Regu-
10 lations, the Federal policy for the protec-
11 tion of human subjects under subpart A of
12 part 46 of title 45, Code of Federal Regu-
13 lations (commonly known as the “Common
14 Rule”), and part 2 of title 42, Code of
15 Federal Regulations (or any successor reg-
16 ulations); and

17 (iii) recommendations for protection
18 of clinical trial participant data against cy-
19 bersecurity threats, as applicable;

20 (C) considerations on data collection meth-
21 ods to help increase recruitment of clinical trial
22 participants and the level of participation of
23 such participants, reduce burden on clinical
24 trial participants, and optimize data quality;

1 (D) recommendations for the use of elec-
2 tronic methods to obtain informed consent from
3 clinical trial participants, taking into consider-
4 ation applicable Federal law, including subpart
5 B of part 50 of title 21, Code of Federal Regu-
6 lations (or successor regulations), and, as ap-
7 propriate, State law;

8 (E) best practices for communication and
9 early engagement between sponsors and the
10 Secretary on the development of data collection
11 methods;

12 (F) the appropriate format to submit such
13 data to the Secretary;

14 (G) a description of the manner in which
15 the Secretary may assess or evaluate data col-
16 lected through digital health technologies to
17 support the development of the drug or device;

18 (H) recommendations regarding the data
19 and information needed to demonstrate that a
20 digital health technology is fit-for-purpose for a
21 clinical trial, and a description of how the Sec-
22 retary will evaluate such data and information;
23 and

24 (I) recommendations for increasing access
25 to, and the use of, digital health technologies in

1 clinical trials to facilitate the inclusion of di-
2 verse and underrepresented populations, as ap-
3 propriate, including considerations for access to,
4 and the use of, digital health technologies in
5 clinical trials by people with disabilities and pe-
6 diatric populations.

7 (b) ADVANCING DECENTRALIZED CLINICAL
8 TRIALS.—

9 (1) IN GENERAL.—Not later than 1 year after
10 the date of enactment of this Act, the Secretary
11 shall issue or revise draft guidance to provide rec-
12 ommendations to clarify and advance the use of de-
13 centralized clinical trials to support the development
14 of drugs and devices and help improve trial partici-
15 pant engagement and advance the use of flexible and
16 novel clinical trial designs. Not later than 18 months
17 after the public comment period on such draft guid-
18 ance ends, the Secretary shall issue a revised draft
19 guidance or final guidance.

20 (2) CONTENT.—The guidance described in
21 paragraph (1) shall include—

22 (A) recommendations for methods of re-
23 mote data collection, including trial participant
24 experience data, though the use of digital health
25 technologies, telemedicine, local laboratories,

1 local health care providers, or other options for
2 data collection;

3 (B) considerations for sponsors to mini-
4 mize or reduce burdens for clinical trial partici-
5 pants associated with participating in a clinical
6 trial, such as the use of digital technologies,
7 telemedicine, local laboratories, local health care
8 providers, or other data collection or assessment
9 options, health care provider home visits, direct-
10 to-participant shipping of investigational drugs
11 and devices, and electronic informed consent, as
12 appropriate;

13 (C) recommendations regarding conducting
14 decentralized clinical trials to facilitate and en-
15 courage diversity among the clinical trial par-
16 ticipants, as appropriate;

17 (D) recommendations for strategies and
18 methods for recruiting, retaining, and engaging
19 with clinical trial participants, including com-
20 munication regarding the role of trial partici-
21 pants and community partners to facilitate clin-
22 ical trial recruitment and engagement, including
23 with respect to diverse and underrepresented
24 populations, as appropriate;

1 (E) considerations for review and oversight
2 by sponsors and institutional review boards, in-
3 cluding remote trial oversight;

4 (F) recommendations for decentralized
5 clinical trial protocol designs and processes for
6 evaluating such proposed trial designs;

7 (G) recommendations for digital health
8 technology and other remote assessment tools
9 that may support decentralized clinical trials,
10 including guidance on appropriate technological
11 platforms and tools, data collection and use,
12 data integrity, and communication to clinical
13 trial participants through such technology;

14 (H) a description of the manner in which
15 the Secretary will assess or evaluate data col-
16 lected within a decentralized clinical trial to
17 support the development of the drug or device,
18 if the manner is different from that used for a
19 non-decentralized trial;

20 (I) considerations for sponsors to validate
21 digital technologies and establish appropriate
22 clinical endpoints for use in decentralized trials;

23 (J) considerations for privacy and security
24 of personally identifiable information of trial
25 participants; and

1 (K) considerations for conducting clinical
2 trials using centralized approaches in conjunc-
3 tion with decentralized approaches.

4 (c) SEAMLESS AND CONCURRENT CLINICAL
5 TRIALS.—

6 (1) IN GENERAL.—Not later than 1 year after
7 the date of enactment of this Act, the Secretary
8 shall issue or revise draft guidance on the use of
9 seamless, concurrent, and other innovative clinical
10 trial designs to support the expedited development
11 and review of applications for drugs, as appropriate.
12 Not later than 18 months after the public comment
13 period on such draft guidance ends, the Secretary
14 shall issue a revised draft guidance or final guid-
15 ance.

16 (2) CONTENT.—The guidance described in
17 paragraph (1) shall include—

18 (A) recommendations on the use of expan-
19 sion cohorts and other seamless clinical trial de-
20 signs to assess different aspects of product can-
21 didates in one continuous trial, including how
22 such clinical trial designs can be used as part
23 of meeting the substantial evidence standard
24 under section 505(d) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355(d));

1 (B) recommendations on the use of clinical
2 trial designs that involve the concurrent con-
3 duct of different or multiple clinical trial
4 phases, and the concurrent conduct of pre-
5 clinical testing, to expedite the development of
6 new drugs and facilitate the timely collection of
7 data;

8 (C) recommendations for how to streamline
9 trial logistics and facilitate the efficient collec-
10 tion and analysis of clinical trial data, including
11 any planned interim analyses and how such
12 analyses could be used to streamline the prod-
13 uct development and review processes;

14 (D) considerations to assist sponsors in en-
15 suring the rights, safety, and welfare of clinical
16 trial participants, maintaining compliance with
17 good clinical practice regulations, minimizing
18 risks to clinical trial data integrity, and ensur-
19 ing the reliability of clinical trial results;

20 (E) recommendations for communication
21 and early engagement between sponsors and the
22 Food and Drug Administration on the develop-
23 ment of seamless, concurrent, or other adaptive
24 trial designs, including review of, and feedback
25 on, clinical trial protocols; and

1 (F) a description of the manner in which
2 the Secretary will assess or evaluate data col-
3 lected through seamless, concurrent, or other
4 adaptive trial designs to support the develop-
5 ment of the drug.

6 (d) INTERNATIONAL HARMONIZATION.—The Sec-
7 retary shall work with foreign regulators pursuant to
8 memoranda of understanding or other arrangements gov-
9 erning the exchange of information to facilitate inter-
10 national harmonization of the regulation and use of decen-
11 tralized clinical trials, digital technology in clinical trials,
12 and seamless, concurrent, and other adaptive or innovative
13 clinical trial designs.

14 **SEC. 503. ACCELERATING COUNTERMEASURE DEVELOP-**
15 **MENT AND REVIEW.**

16 Section 565 of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 360bbb–4) is amended by adding at the
18 end the following:

19 “(h) ACCELERATING COUNTERMEASURE DEVELOP-
20 MENT AND REVIEW DURING AN EMERGENCY.—

21 “(1) ACCELERATION OF COUNTERMEASURE DE-
22 VELOPMENT AND REVIEW.—The Secretary may, at
23 the request of the sponsor of a countermeasure, dur-
24 ing a domestic, military, or public health emergency
25 or material threat described in section

1 564A(a)(1)(C), expedite the development and review
2 of countermeasures that are intended to address
3 such domestic, military, or public health emergency
4 or material threat for approval, licensure, clearance,
5 or authorization under this title or section 351 of
6 the Public Health Service Act.

7 “(2) ACTIONS.—The actions to expedite the de-
8 velopment and review of a countermeasure under
9 paragraph (1) may include the following:

10 “(A) Expedited review of submissions
11 made by sponsors of countermeasures to the
12 Food and Drug Administration, including roll-
13 ing submissions of countermeasure applications
14 and other submissions.

15 “(B) Expedited and increased engagement
16 with sponsors regarding countermeasure devel-
17 opment and manufacturing, including—

18 “(i) holding meetings with the sponsor
19 and the review team and providing timely
20 advice to, and interactive communication
21 with, the sponsor regarding the develop-
22 ment of the countermeasure to ensure that
23 the development program to gather the
24 nonclinical and clinical data necessary for

1 approval, licensure, clearance, or author-
2 ization is as efficient as practicable;

3 “(ii) involving senior managers and
4 experienced review staff, as appropriate, in
5 a collaborative, cross-disciplinary review;

6 “(iii) assigning a cross-disciplinary
7 project lead for the review team to facili-
8 tate;

9 “(iv) taking steps to ensure that the
10 design of the clinical trials is as efficient as
11 practicable, when scientifically appropriate,
12 such as by minimizing the number of pa-
13 tients exposed to a potentially less effica-
14 cious treatment; and

15 “(v) streamlining the review of ap-
16 proved, licensed, cleared, or authorized
17 countermeasures to treat or prevent new or
18 emerging threats, including the review of
19 any changes to such countermeasures.

20 “(C) Expedited issuance of guidance docu-
21 ments and publication of other regulatory infor-
22 mation regarding countermeasure development
23 and manufacturing.

24 “(D) Other steps to expedite the develop-
25 ment and review of a countermeasure applica-

1 tion submitted for approval, licensure, clear-
2 ance, or authorization, as the Secretary deter-
3 mines appropriate.

4 “(3) LIMITATION OF EFFECT.—Nothing in this
5 subsection shall be construed to require the Sec-
6 retary to grant, or take any other action related to,
7 a request of a sponsor to expedite the development
8 and review of a countermeasure for approval, licen-
9 sure, clearance, or authorization under paragraph
10 (1).”.

11 **SEC. 504. THIRD PARTY TEST EVALUATION DURING EMER-**
12 **GENCIES.**

13 (a) IN GENERAL.—Section 565 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360bbb-4), as amend-
15 ed by section 503, is further amended by adding at the
16 end the following:

17 “(i) THIRD PARTY EVALUATION OF TESTS USED
18 DURING AN EMERGENCY.—

19 “(1) IN GENERAL.—For purposes of conducting
20 evaluations regarding whether an in vitro diagnostic
21 product (as defined in section 809.3 of title 21, Code
22 of Federal Regulations (or any successor regula-
23 tions)) for which a request for emergency use au-
24 thorization is submitted under section 564 meets the
25 criteria for issuance of such authorization, the Sec-

1 retary may, as appropriate, consult with persons
2 with appropriate expertise with respect to such eval-
3 uations or enter into cooperative agreements or con-
4 tracts with such persons under which such persons
5 conduct such evaluations and make such rec-
6 ommendations, including, as appropriate, evaluations
7 and recommendations regarding the scope of author-
8 ization and conditions of authorization.

9 “(2) REQUIREMENTS REGARDING EVALUATIONS
10 AND RECOMMENDATIONS.—

11 “(A) IN GENERAL.—In evaluating and
12 making recommendations to the Secretary re-
13 garding the validity, accuracy, and reliability of
14 in vitro diagnostic products, as described in
15 paragraph (1), a person shall consider and doc-
16 ument whether the relevant criteria under sub-
17 section (c)(2) of section 564 for issuance of au-
18 thorization under such section are met with re-
19 spect to the in vitro diagnostic product.

20 “(B) WRITTEN RECOMMENDATIONS.—Rec-
21 ommendations made by a person under this
22 subsection shall be submitted to the Secretary
23 in writing, and shall include the reasons for
24 such recommendation and other information
25 that may be requested by the Secretary.

1 “(3) RULE OF CONSTRUCTION.— Nothing in
2 this subsection shall be construed to require the Sec-
3 retary to consult with, or enter into cooperative
4 agreements or contracts with, persons as described
5 in paragraph (1) for purposes of authorizing an in
6 vitro diagnostic product or otherwise affecting the
7 emergency use authorization authorities under this
8 section or section 564.”.

9 (b) GUIDANCE.—Not later than 1 year after the date
10 of enactment of this Act, the Secretary of Health and
11 Human Services (referred to in this subsection as the
12 “Secretary”) shall issue draft guidance on consultations
13 with persons under subsection (i) of section 565 of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 360bbb–4), as added by subsection (a), including consider-
16 ations concerning conflicts of interest, compensation ar-
17 rangements, and information sharing. Not later than 1
18 year after the public comment period on such draft guid-
19 ance ends, the Secretary shall issue a revised draft guid-
20 ance or final guidance.

21 **SEC. 505. FACILITATING THE USE OF REAL WORLD EVI-**
22 **DENCE.**

23 Not later than 1 year after the date of enactment
24 of this Act, the Secretary of Health and Human Services
25 shall issue or revise existing guidance on considerations

1 for the use of real world data and real world evidence to
2 support regulatory decision-making, as follows:

3 (1) With respect to drugs, such guidance shall
4 address the use of such data and evidence to support
5 the approval of a drug application under section 505
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355) or a biological product application
8 under section 351 of the Public Health Service Act
9 (42 U.S.C. 262), or to support an investigational use
10 exemption under section 505(i) of the Federal Food,
11 Drug, and Cosmetic Act or section 351(a)(3) of the
12 Public Health Service Act. Such guidance shall in-
13 clude considerations for the inclusion, in such appli-
14 cations, of real world data and real world evidence
15 obtained as a result of the use of drugs authorized
16 for emergency use under section 564 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-
18 3), and considerations for standards and methodolo-
19 gies for collection and analysis of real world evidence
20 included in such applications, submissions, or re-
21 quests, as appropriate.

22 (2) With respect to devices, such guidance shall
23 address the use of such data and evidence to support
24 the approval, clearance, or classification of a device
25 pursuant to an application or submission submitted

1 under section 510(k), 513(f)(2), or 515 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 360(k), 360e(f)(2), 360e), to support an investiga-
4 tional use exemption under section 520(g) of such
5 Act (21 U.S.C. 360j(g)), or to support a determina-
6 tion by the Secretary for purposes of section 353 of
7 the Public Health Service Act (42 U.S.C. 263a) (in-
8 cluding the category described under subsection
9 (d)(3) of such section). Such guidance shall include
10 considerations for the inclusion, in such applications,
11 submissions, or requests, of real world data and real
12 world evidence obtained as a result of the use of de-
13 vices authorized for emergency use under section
14 564 of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 360bbb-3), including considerations re-
16 lated to a determination under section 353(d)(3) of
17 the Public Health Service Act (42 U.S.C.
18 263a(d)(3)), and considerations for standards and
19 methodologies for collection and analysis of real
20 world evidence included in such applications, submis-
21 sions, or requests, as appropriate.

22 **SEC. 506. PLATFORM TECHNOLOGIES.**

23 (a) IN GENERAL.—Chapter V of the Federal Food,
24 Drug, and Cosmetic Act is amended by inserting after sec-
25 tion 506J of such Act (21 U.S.C. 356j) the following:

1 **“SEC. 506K. PLATFORM TECHNOLOGIES.**

2 “(a) IN GENERAL.—The Secretary shall establish a
3 process for the designation of platform technologies that
4 meet the criteria described in subsection (b).

5 “(b) CRITERIA.—A platform technology incorporated
6 within or utilized by a drug or biological product is eligible
7 for designation as a designated platform technology under
8 this section if—

9 “(1) the platform technology is incorporated in,
10 or utilized by, a drug approved under section 505 of
11 this Act or a biological product licensed under sec-
12 tion 351 of the Public Health Service Act;

13 “(2) preliminary evidence submitted by the
14 sponsor of the approved or licensed drug described
15 in paragraph (1), or a sponsor that has been grant-
16 ed a right of reference to data submitted in the ap-
17 plication for such drug, demonstrates that the plat-
18 form technology has the potential to be incorporated
19 in, or utilized by, more than one drug without an ad-
20 verse effect on quality, manufacturing, or safety;
21 and

22 “(3) data or information submitted by the ap-
23 plicable person under paragraph (2) indicates that
24 incorporation or utilization of the platform tech-
25 nology has a reasonable likelihood to bring signifi-

1 cant efficiencies to the drug development or manu-
2 facturing process and to the review process.

3 “(c) REQUEST FOR DESIGNATION.—A person may
4 request the Secretary designate a platform technology as
5 a designated platform technology concurrently with, or at
6 any time after, submission under section 505(i) of this Act
7 or section 351(a)(3) of the Public Health Service Act for
8 the investigation of a drug that incorporates or utilizes
9 the platform technology that is the subject of the request.

10 “(d) DESIGNATION.—

11 “(1) IN GENERAL.—Not later than 90 calendar
12 days after the receipt of a request under subsection
13 (c), the Secretary shall determine whether the plat-
14 form technology that is the subject of the request
15 meets the criteria described in subsection (b).

16 “(2) DESIGNATION.—If the Secretary deter-
17 mines that the platform technology meets the cri-
18 teria described in subsection (b), the Secretary shall
19 designate the platform technology as a designated
20 platform technology and may expedite the develop-
21 ment and review of any subsequent application sub-
22 mitted under section 505(b) of this Act or section
23 351(a) of the Public Health Service Act for a drug
24 that uses or incorporates the platform technology
25 pursuant to subsection (e), as appropriate.

1 “(3) DETERMINATION NOT TO DESIGNATE.—If
2 the Secretary determines that the platform tech-
3 nology does not meet the criteria under subsection
4 (b), the Secretary shall include with the determina-
5 tion not to designate the technology a written de-
6 scription of the rationale for such determination.

7 “(4) REVOCATION OF DESIGNATION.—The Sec-
8 retary may revoke a designation made under para-
9 graph (2), if the Secretary determines that the des-
10 ignated platform technology no longer meets the cri-
11 teria described in subsection (b). The Secretary shall
12 communicate the determination to revoke a designa-
13 tion to the requesting sponsor in writing, including
14 a description of the rationale for such determination.

15 “(5) APPLICABILITY.—Nothing in this section
16 shall prevent a product that uses or incorporates a
17 designated platform technology from being eligible
18 for expedited approval pathways if it is otherwise eli-
19 gible under this Act or the Public Health Service
20 Act.

21 “(e) ACTIONS.—The Secretary may take actions to
22 expedite the development and review of an application for
23 a drug that incorporates or utilizes a designated platform
24 technology, including—

1 “(1) engaging in early interactions with the
2 sponsor to discuss the use of the designated plat-
3 form technology and what is known about such tech-
4 nology, including data previously submitted that is
5 relevant to establishing, as applicable, safety or effi-
6 cacy under section 505(b) of this Act or safety, pu-
7 rity, or potency under section 351(a) of the Public
8 Health Service Act;

9 “(2) providing timely advice to, and interactive
10 communication with, the sponsor regarding the de-
11 velopment of the drug that proposes to use the des-
12 ignated platform technology to ensure that the devel-
13 opment program designed to gather data necessary
14 for approval or licensure is as efficient as prac-
15 ticable, which may include holding meetings with the
16 sponsor and the review team throughout the develop-
17 ment of the drug; and

18 “(3) considering inspectional findings, including
19 prior findings, related to the manufacture of a drug
20 that incorporates or utilizes the designated platform
21 technology.

22 “(f) LEVERAGING DATA FROM DESIGNATED PLAT-
23 FORM TECHNOLOGIES.—The Secretary shall, consistent
24 with applicable standards for approval, authorization, or
25 licensure under this Act and section 351(a) of the Public

1 Health Service Act, allow the sponsor of an application
2 under section 505(b) of this Act or section 351(a) of the
3 Public Health Service Act or a request for emergency use
4 authorization under section 564, in order to support ap-
5 proval, licensure, or authorization, to reference or rely
6 upon data and information within such application or re-
7 quest that incorporates or utilizes the same or substan-
8 tially similar platform technology designated under sub-
9 section (d), provided that—

10 “(1) such data and information was submitted
11 by the same sponsor, pursuant to the application for
12 the drug with respect to which designation of the
13 designated platform technology under subsection (d)
14 was granted; or

15 “(2) the sponsor relying on such data and in-
16 formation received a right of reference to such data
17 and information from the sponsor described in para-
18 graph (1).

19 “(g) CHANGES TO A DESIGNATED PLATFORM TECH-
20 NOLOGY.—A sponsor of more than one application ap-
21 proved under section 505(b) of this Act or section 351(a)
22 of the Public Health Service Act for drugs that incor-
23 porate or utilize the same designated platform technology
24 may submit a single supplemental application for the same
25 proposed changes to the designated platform technology

1 that is applicable to more than one drug that incorporates
2 or utilizes such designated platform technology. Such sup-
3 plemental application may be cross referenced in other ap-
4 plications incorporating such change and may include one
5 or more comparability protocols regarding how such
6 changes to the platform technology would be made for
7 each applicable application.

8 “(h) GUIDANCE.—Not later than 1 year after the
9 date of enactment of this section, the Secretary shall issue
10 draft guidance on the implementation of this section. Such
11 guidance shall include examples of drugs that can be man-
12 ufactured using platform technologies, including drugs
13 that contain or consist of vectors and nucleic acids, infor-
14 mation about the Secretary’s review of platform tech-
15 nologies, information regarding submitting for designa-
16 tion, consideration for persons submitting a request for
17 designation who has been granted a right of reference, the
18 implementation of the designated platform technology des-
19 ignation program, efficiencies that may be achieved in the
20 development and review of products that incorporate or
21 utilize designated platform technologies, and recommenda-
22 tions and requirements for making and reporting manu-
23 facturing changes to a designated platform technology in
24 accordance with section 506A.

25 “(i) DEFINITIONS.—For purposes of this section:

1 “(1) The term ‘platform technology’ means—

2 “(A) a technology incorporated into a drug
3 or biological product, such as a nucleic acid se-
4 quence, molecular structure, mechanism of ac-
5 tion, delivery method, vector, or other tech-
6 nology the Secretary determines to be appro-
7 priate, or combination of any such technologies,
8 that—

9 “(i) is essential to the characterization
10 of the drug or biological product; and

11 “(ii) can be adapted for, or incor-
12 porated or utilized in, more than one drug
13 or biological product sharing common
14 structural elements; or

15 “(B) a standardized production or manu-
16 facturing process that is used to create or de-
17 velop more than one drug sharing common
18 structural elements that can be incorporated
19 into multiple different drugs.

20 “(2) The term ‘designated platform technology’
21 means a platform technology that is designated as a
22 platform technology under subsection (d).

23 “(j) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be construed to—

1 “(1) alter the authority of the Secretary to ap-
2 prove drugs pursuant to section 505 of this Act or
3 license biological products pursuant to section 351 of
4 the Public Health Service Act, including standards
5 of evidence and applicable conditions for approval or
6 licensure under the applicable Act; or

7 “(2) confer any new rights with respect to the
8 permissibility of a sponsor of an application for a
9 drug product or biological product referencing infor-
10 mation contained in another application submitted
11 by the holder of an approved application under sec-
12 tion 505(c) of this Act or of a license under section
13 351(a) of the Public Health Service Act.”.

14 (b) REPORT.—Not later than 2 years after the date
15 of enactment of this Act, the Secretary of Health and
16 Human Services shall issue a report to the Committee on
17 Health, Education, Labor, and Pensions of the Senate and
18 the Committee on Energy and Commerce of the House
19 of Representatives, on the platform technology designation
20 program under section 506K of the Federal Food, Drug,
21 and Cosmetic Act, as added by subsection (a). Such report
22 shall include—

23 (1) the number of requests for designation
24 under such program;

1 (2) the number of designations under such pro-
2 gram issued, active, and revoked;

3 (3) the resources required to carry out such
4 program (including the review time used for full-
5 time equivalent employees);

6 (4) any efficiencies gained in the development,
7 manufacturing, and review processes associated with
8 such designations; and

9 (5) recommendations, if any, to strengthen the
10 program to better leverage platform technologies
11 that can be used in more than one drug and meet
12 patient needs in a manner as timely as possible, tak-
13 ing into consideration the resources available to the
14 Secretary of Health and Human Services for car-
15 rying out such program.

16 **SEC. 507. INCREASING EUA DECISION TRANSPARENCY.**

17 Section 564(h)(1) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360bbb-3(h)(1)) is amended—

19 (1) by inserting “on the internet website of the
20 Food and Drug Administration and” after “prompt-
21 ly publish”; and

22 (2) by striking “application under section
23 505(i), 512(j), or 520(g), even if such summary may
24 indirectly reveal the existence of such application”
25 and inserting “application, request, or submission

1 under this section or section 505(b), 505(i), 505(j),
2 512(b), 512(j), 512(n), 515, 510(k), 513(f)(2),
3 520(g), 520(m), 571, or 572 of this Act, or section
4 351(a) or 351(k) of the Public Health Service Act,
5 even if such summary may reveal the existence of
6 such an application, request, or submission, or data
7 contained in such application, request, or submis-
8 sion”.

9 **SEC. 508. IMPROVING FDA GUIDANCE AND COMMUNICA-**
10 **TION.**

11 (a) FDA REPORT AND IMPLEMENTATION OF GOOD
12 GUIDANCE PRACTICES.—The Secretary of Health and
13 Human Services (referred to in this section as the “Sec-
14 retary”) shall develop, and publish on the website of the
15 Food and Drug Administration—

16 (1) a report identifying best practices for the
17 efficient prioritization, development, issuance, and
18 use of guidance documents, within centers, across
19 the Food and Drug Administration, and across other
20 applicable agencies; and

21 (2) a plan for implementation of such best
22 practices, including across other applicable agencies,
23 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 in con-
2 nection with a public health emergency declared
3 under section 319 of the Public Health Service
4 Act (42 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 subsection (j) and (k), respectively;

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.”; and

9 (3) in subsection (j) as so redesignated, by add-
10 ing at the end the following: “Nothing in this section
11 shall be construed to affect the authority of the Sec-
12 retary to require additional information to be in-
13 cluded in a risk management plan pursuant to sub-
14 section (h) other than the information that is other-
15 wise required to be included under such sub-
16 section.”.

17 (b) REPORT.—Not later than 2 years after the date
18 of enactment of this Act, and annually thereafter, the Sec-
19 retary of Health and Human Services shall prepare and
20 submit to the Committee on Health, Education, Labor,
21 and Pensions of the Senate and the Committee on Energy
22 and Commerce of the House of Representatives a report
23 on the use of information manufacturers submit pursuant
24 to section 506J of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 356j) and applicable guidance issued with
2 respect to such section.

3 **SEC. 516. PREVENTING MEDICAL DEVICE SHORTAGES.**

4 (a) NOTIFICATIONS.—Section 506J of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as
6 amended by section 515, is further amended—

7 (1) in the flush text at the end of subsection

8 (a)—

9 (A) by inserting “or any other cir-
10 cumstance” before “that is likely to lead”;

11 (B) by striking “or interruption.” and in-
12 serting “, interruption, or other circumstance.”;

13 (2) in subsection (b)(1), by striking “or inter-
14 rruption” and inserting “, interruption, or other cir-
15 cumstance”;

16 (3) in subsection (c)(1), by inserting “, or other
17 circumstance,” after “manufacture of devices”;

18 (4) in subsection (f), by inserting “or (i)” after
19 “subsection (a)”; and

20 (5) by inserting after subsection (h), as added
21 by section 515, the following:

22 “(i) ADDITIONAL NOTIFICATIONS.—The Secretary
23 may receive voluntary notifications from a manufacturer
24 of a device that is life-supporting, life-sustaining, or in-
25 tended for use in emergency medical care or during sur-

1 gery, or any other device the Secretary determines to be
2 critical to the public health, pertaining to a permanent dis-
3 continuance in the manufacture of the device (except for
4 any discontinuance as a result of an approved modification
5 of the device) or an interruption of the manufacture of
6 the device that is likely to lead to a meaningful disruption
7 in the supply of that device in the United States, and the
8 reasons for such discontinuance or interruption.”.

9 (b) GUIDANCE ON VOLUNTARY NOTIFICATIONS OF
10 DISCONTINUANCE OR INTERRUPTION OF DEVICE MANU-
11 FACTURE.—Not later than 1 year after the date of enact-
12 ment of this Act, the Secretary shall issue draft guidance
13 to facilitate voluntary notifications under subsection (i) of
14 section 506J of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 356j), as added by subsection (a). Such
16 guidance shall include a description of circumstances in
17 which a voluntary notification under such subsection (i)
18 may be appropriate, recommended timeframes for such a
19 notification, the process for receiving such notifications,
20 and actions the Secretary may take to mitigate or prevent
21 a shortage resulting from a discontinuance or interruption
22 in the manufacture of a device for which such notification
23 is received. The Secretary shall issue final guidance not
24 later than 1 year after the close of the comment period
25 for the draft guidance.

1 (c) GUIDANCE ON DEVICE SHORTAGE NOTIFICATION
2 REQUIREMENT.—Not later than 1 year after the date of
3 enactment of this Act, the Secretary shall issue or revise
4 draft guidance regarding requirements under section 506J
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 356j), as amended by this section and section 515. Such
7 guidance shall include a list of each device product code
8 for which a manufacturer of such device is required to no-
9 tify the Secretary in accordance with section 506J.

10 **SEC. 517. REMOTE RECORDS ASSESSMENTS FOR MEDICAL**
11 **DEVICES.**

12 (a) FACTORY INSPECTION.—Section 704(a)(4)(A) of
13 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 374(a)(4)(A)) is amended—

15 (1) in the first sentence, by inserting “or de-
16 vice” after “processing of a drug”; and

17 (2) in the second sentence, by striking “shall
18 include” and all that follows through the period at
19 the end and inserting the following: “shall include—

20 “(A) a description of the records re-
21 quested; and

22 “(B) a rationale for requesting such infor-
23 mation in advance of, or in lieu of, an inspec-
24 tion.”.

1 (b) GUIDANCE.—Not later than 1 year after the date
2 of enactment of this Act, the Secretary shall issue draft
3 guidance describing circumstances in which the Secretary
4 intends to issue requests for records or other information
5 in advance of, or in lieu of, an inspection, processes for
6 responding to such requests electronically or in physical
7 form, and factors the Secretary intends to consider in eval-
8 uating whether such records are provided within a reason-
9 able timeframe, within reasonable limits, and in a reason-
10 able manner, accounting for resource and other limitations
11 that may exist, including for small businesses. The Sec-
12 retary shall issue final guidance not later than 1 year after
13 the close of the comment period for the draft guidance.

14 **SEC. 518. ADVANCED MANUFACTURING TECHNOLOGIES**
15 **DESIGNATION PILOT PROGRAM.**

16 Subchapter A of chapter V of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as
18 amended by section 506, is further amended by inserting
19 after section 506K the following:

20 **“SEC. 506L. ADVANCED MANUFACTURING TECHNOLOGIES**
21 **DESIGNATION PILOT PROGRAM.**

22 “(a) IN GENERAL.—Not later than 1 year after the
23 date of enactment of this section, the Secretary shall ini-
24 tiate a pilot program under which persons may request

1 designation of an advanced manufacturing technology as
2 described in subsection (b).

3 “(b) DESIGNATION PROCESS.—The Secretary shall
4 establish a process for the designation under this section
5 of methods of manufacturing drugs, including biological
6 products, and active pharmaceutical ingredients of such
7 drugs, as advanced manufacturing technologies. A method
8 of manufacturing, or a combination of manufacturing
9 methods, is eligible for designation as an advanced manu-
10 facturing technology if such method or combination of
11 methods incorporates a novel technology, or uses an estab-
12 lished technique or technology in a novel way, that will
13 substantially—

14 “(1) enhance drug quality; or

15 “(2) improve the manufacturing process for a
16 drug and maintain drug quality, including by—

17 “(A) reducing development time for a drug
18 using the designated manufacturing method; or

19 “(B) increasing or maintaining the supply
20 of—

21 “(i) a drug that is life-supporting,
22 life-sustaining, or of critical importance to
23 providing health care; or

24 “(ii) a drug that is on the drug short-
25 age list under section 506E.

1 “(c) EVALUATION AND DESIGNATION OF AN AD-
2 VANCED MANUFACTURING TECHNOLOGY.—

3 “(1) SUBMISSION.—A person who requests des-
4 igation of a method of manufacturing as an ad-
5 vanced manufacturing technology under this section
6 shall submit to the Secretary data or information
7 demonstrating that the method of manufacturing
8 meets the criteria described in subsection (b) in a
9 particular context of use. The Secretary may facili-
10 tate the development and review of such data or in-
11 formation by—

12 “(A) providing timely advice to, and inter-
13 active communication with, such person regard-
14 ing the development of the method of manufac-
15 turing; and

16 “(B) involving senior managers and experi-
17 enced staff of the Food and Drug Administra-
18 tion, as appropriate, in a collaborative, cross-
19 disciplinary review of the method of manufac-
20 turing, as applicable.

21 “(2) EVALUATION AND DESIGNATION.—Not
22 later than 180 calendar days after the receipt of a
23 request under paragraph (1), the Secretary shall de-
24 termine whether to designate such method of manu-
25 facturing as an advanced manufacturing technology,

1 in a particular context of use, based on the data and
2 information submitted under paragraph (1) and the
3 criteria described in subsection (b).

4 “(d) REVIEW OF ADVANCED MANUFACTURING
5 TECHNOLOGIES.—If the Secretary designates a method of
6 manufacturing as an advanced manufacturing technology,
7 the Secretary shall—

8 “(1) expedite the development and review of an
9 application submitted under section 505 of this Act
10 or section 351 of the Public Health Service Act, in-
11 cluding supplemental applications, for drugs that are
12 manufactured using a designated advanced manufac-
13 turing technology; and

14 “(2) allow the holder of an advanced technology
15 designation, or a person authorized by the advanced
16 manufacturing technology designation holder, to ref-
17 erence or rely upon, in an application submitted
18 under section 505 of this Act or section 351 of the
19 Public Health Service Act, including a supplemental
20 application, data and information about the des-
21 ignated advanced manufacturing technology for use
22 in manufacturing drugs in the same context of use
23 for which the designation was granted.

24 “(e) IMPLEMENTATION AND EVALUATION OF AD-
25 VANCED MANUFACTURING TECHNOLOGIES PILOT.—

1 “(1) PUBLIC MEETING.—The Secretary shall
2 publish in the Federal Register a notice of a public
3 meeting, to be held not later than 180 days after the
4 date of enactment of this section, to discuss, and ob-
5 tain input and recommendations from relevant
6 stakeholders regarding—

7 “(A) the goals and scope of the pilot pro-
8 gram, and a suitable framework, procedures,
9 and requirements for such program; and

10 “(B) ways in which the Food and Drug
11 Administration will support the use of advanced
12 manufacturing technologies and other innova-
13 tive manufacturing approaches for drugs.

14 “(2) PILOT PROGRAM GUIDANCE.—

15 “(A) IN GENERAL.—The Secretary shall—

16 “(i) not later than 180 days after the
17 public meeting under paragraph (1), issue
18 draft guidance regarding the goals and im-
19 plementation of the pilot program under
20 this section; and

21 “(ii) not later than 2 years after the
22 date of enactment of this section, issue
23 final guidance regarding the implementa-
24 tion of such program.

1 “(B) CONTENT.—The guidance described
2 in subparagraph (A) shall address—

3 “(i) the process by which a person
4 may request a designation under sub-
5 section (b);

6 “(ii) the data and information that a
7 person requesting such a designation is re-
8 quired to submit under subsection (c), and
9 how the Secretary intends to evaluate such
10 submissions;

11 “(iii) the process to expedite the de-
12 velopment and review of applications under
13 subsection (d); and

14 “(iv) the criteria described in sub-
15 section (b) for eligibility for such a des-
16 ignation.

17 “(3) REPORT.—Not later than 3 years after the
18 date of enactment of this section and annually there-
19 after, the Secretary shall publish on the website of
20 the Food and Drug Administration and submit to
21 the Committee on Health, Education, Labor, and
22 Pensions of the Senate and the Committee on En-
23 ergy and Commerce of the House of Representatives
24 a report containing a description and evaluation of
25 the pilot program being conducted under this sec-

1 tion, including the types of innovative manufacturing
2 approaches supported under the program. Such re-
3 port shall include the following:

4 “(A) The number of persons that have re-
5 quested designations and that have been grant-
6 ed designations.

7 “(B) The number of methods of manufac-
8 turing that have been the subject of designation
9 requests and that have been granted designa-
10 tions.

11 “(C) The average number of calendar days
12 for completion of evaluations under subsection
13 (c)(2).

14 “(D) An analysis of the factors in data
15 submissions that result in determinations to
16 designate and not to designate after evaluation
17 under subsection (c)(2).

18 “(E) The number of applications received
19 under section 505 of this Act or section 351 of
20 the Public Health Service Act, including supple-
21 mental applications, that have included an ad-
22 vanced manufacturing technology designated
23 under this section, and the number of such ap-
24 plications approved.

25 “(f) SUNSET.—The Secretary—

1 “(1) may not consider any requests for designa-
2 tion submitted under subsection (c) after October 1,
3 2029; and

4 “(2) may continue all activities under this sec-
5 tion with respect to advanced manufacturing tech-
6 nologies that were designated pursuant to subsection
7 (d) prior to such date, if the Secretary determines
8 such activities are in the interest of the public
9 health.”.

10 **SEC. 519. TECHNICAL CORRECTIONS.**

11 (a) TECHNICAL CORRECTIONS TO THE CARES
12 ACT.—Division A of the CARES Act (Public Law 116–
13 136) is amended—

14 (1) in section 3111(1), by striking “in para-
15 graph (1)” and inserting “in the matter preceding
16 paragraph (1)”;

17 (2) in section 3112(d)(1), by striking “and sub-
18 paragraphs (A) and (B)” and inserting “as subpara-
19 graphs (A) and (B)”;

20 (3) in section 3112(e), by striking “Federal
21 Food, Drug, Cosmetic Act” and inserting “Federal
22 Food, Drug, and Cosmetic Act”.

23 (b) TECHNICAL CORRECTIONS TO THE FEDERAL
24 FOOD, DRUG, AND COSMETIC ACT RELATED TO THE
25 CARES ACT.—

1 (1) SECTION 506C.—Section 506C(a) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 356c(a)) is amended, in the flush text at the end, by
4 striking the second comma after “in the United
5 States”.

6 (2) EFFECTIVE DATE.—The amendment made
7 by paragraph (1) shall take effect as if included in
8 section 3112 of division A of the CARES Act (Pub-
9 lic Law 116–136).

10 (c) OTHER TECHNICAL CORRECTION TO THE FED-
11 ERAL FOOD, DRUG, AND COSMETIC ACT.—Section
12 505B(f)(6)(I) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 355c(f)(6)(I)) is amended by striking
14 “subsection (a)(3)(B)” and inserting “subsection
15 (a)(4)(C)”.