

117TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Prepare for and Respond to Existing Viruses, Emerging
6 New Threats, and Pandemics Act” or the “PREVENT
7 Pandemics Act”.

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

Sec. 1. Short title; table of contents.

2

TITLE I—STRENGTHENING FEDERAL AND STATE
PREPAREDNESS

Subtitle A—Federal Leadership and Accountability

- Sec. 101. Comprehensive review of the COVID–19 response.
- Sec. 102. Appointment and authority of the Director of the Centers for Disease Control and Prevention.
- Sec. 103. Public health and medical preparedness and response coordination.
- Sec. 104. Strengthening public health communication.

Subtitle B—State and Local Readiness

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

TITLE II—IMPROVING PUBLIC HEALTH PREPAREDNESS AND
RESPONSE CAPACITYSubtitle 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 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.

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.

Subtitle D—Improving Public Health Responses

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

TITLE III—ACCELERATING RESEARCH AND COUNTERMEASURE
DISCOVERY

- 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.

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. Strategic National Stockpile contract duration.
- Sec. 407. Reimbursement for certain supplies.
- Sec. 408. Action reporting on stockpile depletion.
- Sec. 409. Provision of medical countermeasures to Indian programs and facilities.
- Sec. 410. Grants for State strategic stockpiles.

TITLE V—ENHANCING DEVELOPMENT AND COMBATING
SHORTAGES OF MEDICAL PRODUCTS

Subtitle A—Development and Review

- Sec. 501. Advancing qualified infectious disease product innovation.
- Sec. 502. Modernizing clinical trials.
- Sec. 503. Accelerating countermeasure development and review.
- Sec. 504. Third party test evaluation during emergencies.
- Sec. 505. Facilitating the use of real world evidence.
- Sec. 506. Advanced 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 a task force to be known as the “National Task
10 Force on the Response of the United States to the
11 COVID-19 Pandemic” (referred to in this section as the
12 “Task Force”).

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

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

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

20 (B) the ongoing Federal, State, local, and
21 territorial responses in the United States, in-
22 cluding the activities, policies, and decisions of
23 the Trump Administration and the Biden Ad-
24 ministration;

1 (C) the impact of the pandemic on public
2 health and health care systems; and

3 (D) the initial outbreak in Wuhan, China,
4 including efforts to determine the potential
5 causes for the emergence of the SARS-CoV-2
6 virus, and Federal actions to mitigate its spread
7 internationally;

8 (2) build upon existing or ongoing evaluations
9 and avoid unnecessary duplication, by reviewing the
10 findings, conclusions, and recommendations of other
11 appropriate task forces, committees, commissions, or
12 entities established by other public or nonprofit pri-
13 vate entities related to the United States' prepared-
14 ness for, and response to, the COVID-19 pandemic;

15 (3) identify gaps in public health preparedness
16 and medical response policies, processes, and activi-
17 ties and how such gaps impacted the ability of the
18 United States to respond to the COVID-19 pan-
19 demic; and

20 (4) submit a report to the President and to
21 Congress on its findings, conclusions, and rec-
22 ommendations to improve the United States' pre-
23 paredness for, and response to, future public health
24 emergencies, including a public health emergency re-
25 sulting from an emerging infectious disease.

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

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

4 (A) 1 member shall be appointed by the
5 majority leader of the Senate;

6 (B) 1 member shall be appointed by the
7 minority leader of the Senate;

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

11 (D) 2 members shall be appointed by the
12 ranking member of the Committee on Health,
13 Education, Labor, and Pensions of the Senate;

14 (E) 1 member shall be appointed by the
15 Speaker of the House of Representatives;

16 (F) 1 member shall be appointed by the
17 minority leader of the House of Representa-
18 tives;

19 (G) 2 members shall be appointed by the
20 chair of the Committee on Energy and Com-
21 merce of the House of Representatives; and

22 (H) 2 members shall be appointed by the
23 ranking member of the Committee on Energy
24 and Commerce of the House of Representatives.

1 (2) CHAIR AND VICE CHAIR.—Not later than 30
2 days after the date on which all members of the
3 Task Force are appointed under paragraph (1), such
4 members shall meet to elect a Chair and Vice Chair
5 from among such members. The Chair and Vice
6 Chair shall each be elected to serve upon an affirma-
7 tive vote from 8 members of the Task Force. The
8 Chair and Vice Chair shall not be registered mem-
9 bers of the same political party.

10 (3) QUALIFICATIONS.—

11 (A) POLITICAL PARTY AFFILIATION.—Not
12 more than 6 members of the Task Force shall
13 be registered members of the same political
14 party.

15 (B) NONGOVERNMENTAL APPOINTEES.—
16 An individual appointed to the Task Force may
17 not be an officer or employee of the Federal
18 Government or any State, local, or Tribal gov-
19 ernment.

20 (C) QUALIFICATIONS.—It is the sense of
21 Congress that individuals appointed to the Task
22 Force should be highly qualified citizens of the
23 United States. Members appointed under para-
24 graph (1) may include individuals with expertise
25 in—

1 (i) public health, health disparities
2 and at-risk populations, medicine, and re-
3 lated fields;

4 (ii) State, local, Tribal, or territorial
5 government, including public health and
6 medical preparedness and response and
7 emergency management and other relevant
8 public administration;

9 (iii) research regarding, or the devel-
10 opment, manufacturing, distribution, and
11 regulation of, medical products;

12 (iv) national security and foreign rela-
13 tions, including global health; and

14 (v) commerce, including transpor-
15 tation, supply chains, and small business.

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

20 (5) MEETINGS.—The Task Force shall meet
21 and begin the operations of the Task Force as soon
22 as practicable. After its initial meeting, the Task
23 Force shall meet upon the call of the Chair and Vice
24 Chair or 8 of its members.

25 (6) QUORUM; VACANCIES.—

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

3 (B) VACANCIES.—Any vacancy in the Task
4 Force shall not affect its powers, but shall be
5 filled in the same manner in which the original
6 appointment was made.

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

9 (1) conduct a review that—

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

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

15 (ii) seeking access to relevant records;

16 and

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

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

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

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

9 (ii) relevant actions taken by, and co-
10 ordination between, Federal, State, local,
11 Tribal, and territorial governments on pre-
12 paredness and response efforts, including
13 coordination between governments and
14 other public and private entities, during
15 the—

16 (I) initial response in the United
17 States;

18 (II) response during the Trump
19 Administration; and

20 (III) ongoing response during the
21 Biden Administration;

22 (iii) communication of public health
23 and scientific information related to the
24 COVID–19 pandemic, including processes
25 for the development, approval, and dis-

1 semination of Federal public health and
2 other relevant public health or scientific
3 guidance;

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

9 (C) may include assessments relating to—

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

14 (ii) the capacity and capabilities of
15 health care facilities and the health care
16 workforce to respond to the COVID–19
17 pandemic;

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

22 (iv) international preparedness for
23 and response to COVID–19, and Federal
24 decision-making processes related to new
25 global health threats;

1 (v) containment and mitigation meas-
2 ures related to international travel in re-
3 sponse to COVID–19; and

4 (vi) the impact of the COVID–19 pan-
5 demic on, and mitigation efforts with re-
6 spect to, hard-to-reach and at-risk or un-
7 derserved populations; and;

8 (2) identify, review, and evaluate the lessons
9 learned from the COVID–19 pandemic, including ac-
10 tivities to prepare for, and respond to, future poten-
11 tial pandemics and related public health emer-
12 gencies; and

13 (3) submit to the President and Congress such
14 reports as are required by this Act containing such
15 findings, conclusions, and recommendations as the
16 Task Force shall determine.

17 (e) POWERS OF TASK FORCE.—

18 (1) HEARINGS.—The Task Force may—

19 (A) hold such hearings and sit and act at
20 such times and places, take such testimony, re-
21 ceive such evidence as determined by the Chair
22 and Vice Chair, and administer such oaths as
23 the Task Force or a designated member, as de-
24 termined by the Chair or Vice Chair, may de-

1 termine advisable to be necessary to carry out
2 the functions of the Task Force; and

3 (B) subject to paragraph (2)(A), require,
4 by subpoena or otherwise, the attendance and
5 testimony of such witnesses and the production
6 of such books, records, correspondence, memo-
7 randa, papers, and documents, as the person
8 described in paragraph (2)(A)(i) may determine
9 advisable.

10 **[(2) SUBPOENAS.—**

11 **[(A) ISSUANCE.—**

12 **[(i) IN GENERAL.—**A subpoena may
13 be issued under this subsection only—**]**

14 **[(I) by the agreement of the**
15 **Chair and the Vice Chair; or]**

16 **[(II) by the affirmative vote of 9**
17 **members of the Task Force.]**

18 **[(ii) SIGNATURE.—**Subpoenas issued
19 under this subsection may be issued under
20 the signature of the Chair or any member
21 designated by a majority of the Task
22 Force, and may be served by any person
23 designated by the Chair or by a member
24 designated by agreement of the majority of
25 the Task Force.**]**

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

13 **(3) CONTRACTING.—**The Task Force may, to
14 such extent and in such amounts as are provided in
15 appropriation Acts, enter into contracts to enable
16 the Task Force to discharge its duties under this
17 Act.

18 **[(4) INFORMATION FROM FEDERAL AGEN-**
19 **CIES.—**

20 **[(A) IN GENERAL.—**The Task Force may
21 access, to the extent authorized by law, from
22 any executive department, bureau, agency,
23 board, commission, office, independent estab-
24 lishment, or instrumentality of the Federal Gov-
25 ernment, such information, documents, sugges-

1 tions, estimates, and statistics as the Task
2 Force considers necessary to carry out this sec-
3 tion.】

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

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

16 (5) ASSISTANCE FROM FEDERAL AGENCIES.—

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

24 (B) OTHER DEPARTMENTS AND AGEN-
25 CIES.—In addition to the assistance provided

1 for in subparagraph (A), departments and
2 agencies of the United States may provide to
3 the Task Force such assistance as such depart-
4 ments and agencies may determine advisable
5 and as authorized by law.

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

11 (A) the name of the entity that provided
12 such donation;

13 (B) the service or property provided
14 through such donation;

15 (C) the value of such donation; and

16 (D) how the Task Force plans to use such
17 donation.

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

22 (f) APPLICABILITY OF FEDERAL ADVISORY COM-
23 MITTEE ACT.—

1 (1) IN GENERAL.—The Federal Advisory Com-
2 mittee Act (5 U.S.C. App.) shall apply to the Task
3 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 COMPENSA-**
21 **TION.—**The Chair of the Task Force, in agree-
22 ment with the Vice Chair, in accordance with
23 rules agreed upon by the Task Force, may ap-
24 point and fix the compensation of a staff direc-
25 tor and such other personnel as may be nec-

1 essary to enable the Task Force to carry out its
2 functions, without regard to the provisions of
3 title 5, United States Code, governing appoint-
4 ments in the competitive service, and without
5 regard to the provisions of chapter 51 and sub-
6 chapter III of chapter 53 of such title relating
7 to classification and General Schedule pay
8 rates, except that no rate of pay fixed under
9 this subsection may exceed the equivalent of
10 that payable for a position at level V of the Ex-
11 ecutive Schedule under section 5316 of title 5,
12 United States 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) TRAVEL EXPENSES.—Each member of the Task
17 Force shall serve without compensation, but shall receive
18 travel expenses, including per diem in lieu of subsistence,
19 at rates authorized for an employee of an agency under
20 subchapter I of chapter 57 of title 5, United States Code.】

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

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

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

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

16 (2) FINAL REPORT.—

17 (A) IN GENERAL.—Not later than one year
18 after the date of enactment of this Act, the
19 Task Force shall submit to the President, the
20 Committee on Health, Education, Labor, and
21 Pensions of the Senate, and the Committee on
22 Energy and Commerce of the House of Rep-
23 resentatives a final report containing such find-
24 ings, conclusions, and recommendations as have
25 been agreed to by 8 members of the Task

1 Force. The final report shall be made available
2 online in a manner that does not compromise
3 national security.

4 (B) EXTENSIONS.—

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

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

17 (C) SPECIAL RULES AND CONSIDER-
18 ATIONS.—

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

24 (ii) SPECIAL TIMING CONSIDER-
25 ATIONS.—Notwithstanding any other pro-

1 vision of this section, the Task Force shall
2 not publish or make available any interim
3 or final report during the during the 60-
4 day periods ending November 8, 2022, and
5 November 5, 2024.

6 (3) TERMINATION.—

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

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

18 (k) FUNDING.—

19 (1) AUTHORIZATION OF APPROPRIATIONS.—
20 There is authorized to be appropriated to carry out
21 this section, a total of \$3,000,000 for fiscal years
22 2022 and 2023.

23 (2) DURATION OF AVAILABILITY.—Amounts
24 made available to the Task Force under paragraph

1 (1) shall remain available until the termination of
2 the Task Force.

3 (l) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed to confer on Task Force purposes
5 or duties that are the responsibility of Congress.

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

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

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

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

1 shall perform functions provided for in subsection (b) and
2 such other functions as the Secretary may prescribe.

3 “(b) FUNCTIONS.—The Secretary, acting through the
4 Director, shall—

5 “(1) implement and exercise applicable authori-
6 ties and responsibilities provided for in this Act or
7 other applicable law related to the investigation, de-
8 tection, identification, prevention, or control of dis-
9 eases or conditions to preserve and improve public
10 health;

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, and laboratory capacity and
22 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 “(4) REPORT.—Not later than 3 years after the
24 issuance of the initial CDC Strategic Plan under
25 this subsection, and every 3 years thereafter, the

1 Comptroller General of the United States shall sub-
2 mit to the Committee on Health, Education, Labor,
3 and Pensions of the Senate and the Committee on
4 Energy and Commerce of the House of Representa-
5 tives a report on the extent to which the programs
6 and activities of the CDC align with and support
7 strategies from the CDC Strategic Plan, and how
8 such programs and activities advance the capabilities
9 and capacity of the CDC and State, local, and Trib-
10 al health departments, as applicable, to achieve the
11 strategic priorities established under paragraph
12 (2)(A). Such report shall include updates on
13 progress in achieving performance measures, includ-
14 ing identification of any challenges related to evalua-
15 tion or achievement of performance targets.

16 “(d) APPEARANCES BEFORE CONGRESS.—

17 “(1) IN GENERAL.—Each fiscal year, the Direc-
18 tor shall appear before the Committee on Health,
19 Education, Labor, and Pensions of the Senate and
20 the Committee on Energy and Commerce of the
21 House of Representatives at hearings on topics such
22 as—

23 “(A) support for State, local, and Tribal
24 public health preparedness and responses to any

1 recent or ongoing public health emergency, in-
2 cluding—

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

11 “(ii) any objectives and planned ac-
12 tivities for the upcoming fiscal year to ad-
13 dress gaps in, or otherwise improve, State,
14 local, and Tribal public health prepared-
15 ness; and

16 “(iii) other potential all-hazard
17 threats that the Director is preparing to
18 address;

19 “(B) activities related to public health and
20 functions of the Director described in sub-
21 section (b); and

22 “(C) updates on other relevant activities
23 supported or conducted by the CDC, or in col-
24 laboration or coordination with the heads of

1 other Federal departments, agencies, or stake-
2 holders, as appropriate.

3 “(2) CLARIFICATIONS.—

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

12 “(B) SCOPE OF REQUIREMENTS.—The re-
13 quirements of this subsection shall not be con-
14 strued to impact the appearance of other Fed-
15 eral officials or the Director at hearings of ei-
16 ther Committee described in paragraph (1) at
17 other times and for purposes other than the
18 times and purposes described in paragraph (1).

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

24 (b) APPLICATION.—The first sentence of section
25 305(a) of the Public Health Service Act, as added by sub-

1 section (a), shall not apply to the Director of the Centers
2 for Disease Control and Prevention who is serving on the
3 date of enactment of this Act.

4 **SEC. 103. PUBLIC HEALTH AND MEDICAL PREPAREDNESS**
5 **AND RESPONSE COORDINATION.**

6 (a) PUBLIC HEALTH EMERGENCY FUND.—Section
7 319(b) of the Public Health Service Act (42 U.S.C.
8 247d(b)) is amended—

9 (1) in paragraph (2)—

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

12 (B) by redesignating subparagraph (F) as
13 subparagraph (G); and

14 (C) by inserting after subparagraph (E),
15 the following:

16 “(F) support the initial deployment and
17 distribution of contents of the Strategic Na-
18 tional Stockpile, as appropriate; and”;

19 (2) by amending paragraph (3)(A) to read as
20 follows:

21 “(A) the expenditures made from the Pub-
22 lic Health Emergency Fund in such fiscal year,
23 including—

24 “(i) the amount obligated;

1 “(ii) the recipient or recipients of such
2 obligated funds;

3 “(iii) the specific response activities
4 such obligated funds will support; and

5 “(iv) the declared or potential public
6 health emergency for which such funds
7 were obligated; and”.

8 (b) IMPROVING PUBLIC HEALTH AND MEDICAL PRE-
9 PAREDNESS AND RESPONSE COORDINATION.—

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

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

1 “(iii) coordinating efforts to support
2 or establish new capabilities, as appro-
3 priate.”; and

4 (ii) in subparagraph (G)—

5 (I) by redesignating clauses (i)
6 and (ii) as subclauses (I) and (II) and
7 adjusting the margins accordingly;

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

10 (aa) by inserting “each year,
11 including national-level and
12 State-level full-scale exercises not
13 less than once every 5 years”
14 after “operational exercises”; and

15 (bb) by striking “exercises
16 based on—” and inserting “exer-
17 cises—

18 “(i) based on”;

19 (III) by striking the period and
20 inserting a semicolon; and

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

23 “(ii) that assess the ability of the
24 Strategic National Stockpile, as appro-
25 priate, to provide medical countermeasures,

1 medical products, and other supplies, in-
2 cluding ancillary medical supplies, to sup-
3 port the response to a public health emer-
4 gency or potential public health emergency,
5 including a threat that requires the large-
6 scale and simultaneous deployment of
7 stockpiles and a long-term public health
8 and medical response; and

9 “(iii) conducted in coordination with
10 State and local health officials.”.

11 (c) APPEARANCES BEFORE AND REPORTS TO CON-
12 GRESS.—Section 2811 of the Public Health Service Act
13 (42 U.S.C. 300hh–10) is amended by adding at the end
14 the following:

15 “(g) APPEARANCES BEFORE CONGRESS.—

16 “(1) IN GENERAL.—Each fiscal year, the As-
17 sistant Secretary for Preparedness and Response
18 shall appear before the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate and the
20 Committee on Energy and Commerce of the House
21 of Representatives at hearings, on topics such as—

22 “(A) coordination of Federal activities to
23 prepare for, and respond to, public health emer-
24 gencies;

1 “(B) maintenance activities and capabili-
2 ties of the Strategic National Stockpile, includ-
3 ing whether, and the degree to which, rec-
4 ommendations made pursuant to section 2811-
5 1(e)(1)(A) have been met;

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

8 “(D) activities implementing the counter-
9 measures budget plan described under sub-
10 section (b)(7), including—

11 “(i) any challenges in meeting the full
12 range of identified medical countermeasure
13 needs; and

14 “(ii) progress in supporting advanced
15 research, development, and procurement of
16 medical countermeasures, pursuant to sub-
17 section (b)(3);

18 “(E) the strategic direction of, and activi-
19 ties related to, the sustainment of manufac-
20 turing surge capacity and capabilities for med-
21 ical countermeasures pursuant to section 319L;

22 “(F) any additional objectives, activities,
23 or initiatives that have been carried out or are
24 planned by the Assistant Secretary for Pre-

1 paredness and Response and associated chal-
2 lenges, as appropriate;

3 “(G) the specific all-hazards threats that
4 the Assistant Secretary for Preparedness and
5 Response is preparing to address, or that are
6 being addressed, through the activities de-
7 scribed in subparagraphs (A) through (F); and

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

13 “(2) CLARIFICATIONS.—

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

22 “(B) SCOPE OF REQUIREMENTS.—The re-
23 quirements of this subsection shall not be con-
24 strued to impact the appearance of other Fed-
25 eral officials or the Assistant Secretary at hear-

1 ings of either Committee described in para-
2 graph (1) at other times and for purposes other
3 than the times and purposes described in para-
4 graph (1)

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

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

14 “(d) ANNUAL REPORT ON EMERGENCY RESPONSE
15 AND PREPAREDNESS.—The Secretary shall submit a writ-
16 ten report each fiscal year to the Committee on Health,
17 Education, Labor, and Pensions of the Senate and the
18 Committee on Energy and Commerce of the House of
19 Representatives, containing updated information related
20 to an assessment of the response to any public health
21 emergency declared, or otherwise in effect, during, the pre-
22 vious fiscal year, and the state of public health prepared-
23 ness and response capabilities for chemical, biological, ra-
24 diological, and nuclear threats, including emerging infec-

1 tious diseases, and any challenges in preparing for or re-
2 sponding to such threats, as appropriate.”.

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

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

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

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

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

22 (D) gaps, if any, in interagency agree-
23 ments that prevent the Secretary from carrying
24 out the goals under section 2802 of the Public
25 Health Service Act (42 U.S.C. 300hh-1);

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

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

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

11 (3) submit to 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 a report on the reviews under
15 paragraphs (1) and (2), including related rec-
16 ommendations, as applicable.

17 **SEC. 104. STRENGTHENING PUBLIC HEALTH COMMUNICA-**
18 **TION.**

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

22 “(b) PUBLIC HEALTH INFORMATION AND COMMU-
23 NICATIONS ADVISORY COMMITTEE.—

24 “(1) IN GENERAL.—The Secretary shall estab-
25 lish an advisory committee to be known as the Pub-

1 lic Health Information and Communications Advi-
2 sory Committee (referred to in this subsection as the
3 ‘Advisory Committee’).

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

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

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

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

17 “(iii) other relevant factors, as the
18 Secretary determines appropriate;

19 “(B) information from academic institu-
20 tions, community-based organizations, and
21 other nongovernmental organizations related to
22 evidence-based or evidence-informed strategies
23 and best practices to effectively communicate
24 and disseminate such information;

1 “(C) strategies to improve communication
2 and dissemination of scientific and evidence-
3 based public health information to the public,
4 and, as appropriate, to address misinformation
5 during public health emergencies, including
6 strategies to—

7 “(i) identify the most effective meth-
8 ods for the dissemination of information
9 during a public health emergency;

10 “(ii) determine best practices and
11 communicate information to populations
12 that may be impacted by such misinforma-
13 tion; and

14 “(iii) adapt approaches for the dis-
15 semination of information, as appropriate,
16 to address emerging trends related to mis-
17 information.

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

20 “(A) appropriate Federal officials, ap-
21 pointed by the Secretary, who shall serve as
22 nonvoting members; and

23 “(B) individuals, appointed by the Sec-
24 retary, with expertise in public health, medicine,
25 communications, related technology, psychology,

1 national security, and other areas, as the Sec-
2 retary determines appropriate, who shall serve
3 as voting members.

4 “(4) DISSEMINATION.—The Secretary shall re-
5 view the recommendations of the Advisory Com-
6 mittee and, not later than 180 days after receipt of
7 the report under paragraph (2), 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 any actions planned by the Secretary
12 related to the communication and dissemination of
13 scientific and evidence-based public health informa-
14 tion, including addressing misinformation, as appro-
15 priate.

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

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 the Assistant Secretary for Pre-
17 paredness and Response, as appropriate, in pre-
18 paring for, and responding to, a public health emer-
19 gency;”.

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

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

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

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

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

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

14 (1) by redesignating paragraphs (4) through
15 (7) as paragraphs (5) through (8), respectively;

16 (2) by inserting after paragraph (3) the fol-
17 lowing:

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

23 (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 of the Senate and the Committee on Energy
13 and Commerce of the House of Representatives, reflecting
14 the feedback of the advisory councils for the Center for
15 Substance Abuse Treatment, the Center for Substance
16 Abuse Prevention, and the Center for Mental Health Serv-
17 ices, pursuant to section 502 of the Public Health Service
18 Act (42 U.S.C. 290aa–1), with recommendations to im-
19 prove the continued provision of mental health and sub-
20 stance use disorder services during a public health emer-
21 gency declared under section 319 of such Act (42 U.S.C.
22 247d), and the provision of such services as part of the
23 public health and medical response to such an emergency,
24 consistent with title XXVIII of such Act (42 U.S.C. 300hh
25 et seq.).

1 (e) GAO REPORT.—Not later than 3 years after the
2 date of enactment of this Act, the Comptroller General
3 of the United States shall submit to the Committee on
4 Health, Education, Labor, and Pensions of the Senate and
5 the Committee on Energy and Commerce of the House
6 of Representatives a report on programs and activities of
7 the Substance Abuse and Mental Health Services Admin-
8 istration to support the continued provision of mental
9 health and substance use disorder services and related ac-
10 tivities during the COVID–19 pandemic, including the
11 provision of such services as part of the medical and public
12 health response to such pandemic. Such report shall—

13 (1) examine the role played by the advisory
14 councils described in section 502 of the Public
15 Health Service Act (42 U.S.C. 290aa–1) and the
16 National Mental Health and Substance Use Policy
17 Laboratory established under section 501A of such
18 Act (42 U.S.C. 290aa–0) in providing technical as-
19 sistance and recommendations regarding the activi-
20 ties to support the response of the Substance Abuse
21 and Mental Health Services Administration to the
22 public health emergency declared under section 319
23 of the Public Health Service Act (42 U.S.C. 247d)
24 with respect to COVID–19;

1 (2) describe the manner in which existing
2 awardees of mental health and substance use dis-
3 order programs altered delivery of services during
4 such public health emergency; and

5 (3) describe activities of the Substance Abuse
6 and Mental Health Services Administration to sup-
7 port the response to such public health emergency,
8 including through technical assistance, provision of
9 services, and any flexibilities provided to such exist-
10 ing awardees.

11 **SEC. 113. TRAUMA CARE REAUTHORIZATION.**

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

14 (1) in subsection (a)—

15 (A) in paragraph (3)—

16 (i) by inserting “analyze,” after “com-
17 pile,”; and

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

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

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

23 (D) by redesignating paragraph (6) as
24 paragraph (5);

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

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

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

15 “(1) developing, issuing, and updating guid-
16 ance, as appropriate, to support the coordinated
17 medical triage and evacuation to appropriate medical
18 institutions based on patient medical need, taking
19 into account regionalized systems of care;

20 “(2) disseminating, as appropriate, information
21 on evidence-based or evidence-informed trauma care
22 practices, taking into consideration emergency med-
23 ical services and trauma care systems, including
24 such practices identified through activities conducted
25 under subsection (a) and which may include the

1 identification and dissemination of performance
2 metrics, as applicable and appropriate; and

3 “(3) other activities, as appropriate, to optimize
4 a coordinated and flexible approach to the emer-
5 gency response and medical surge capacity of hos-
6 pitals, other health care facilities, critical care, and
7 emergency medical systems.”.

8 (b) GRANTS TO IMPROVE TRAUMA CARE IN RURAL
9 AREAS.—Section 1202 of the Public Health Service Act
10 (42 U.S.C. 300d–3) is amended—

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

14 (2) by amending subsections (a) and (b) to read
15 as follows:

16 “(a) IN GENERAL.—The Secretary shall award
17 grants to eligible entities for the purpose of carrying out
18 research and demonstration projects to support the im-
19 provement of emergency medical services and trauma care
20 in rural areas through the development of innovative uses
21 of technology, training and education, transportation of
22 seriously injured patients for the purposes of receiving
23 such emergency medical services, access to prehospital
24 care, evaluation of protocols for the purposes of improve-
25 ment of outcomes and dissemination of any related best

1 practices, activities to facilitate clinical research, as appli-
2 cable and appropriate, and increasing communication and
3 coordination with applicable State or Tribal trauma sys-
4 tems.

5 “(b) ELIGIBLE ENTITIES.—

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

10 “(2) PRIORITY.—In awarding grants under this
11 section, the Secretary shall give priority to eligible
12 entities that will provide services under the grant in
13 any rural area identified by a State under section
14 1214(d)(1).”; and

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

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

20 (c) PILOT GRANTS FOR TRAUMA CENTERS.—Section
21 1204 of the Public Health Service Act (42 U.S.C. 300d–
22 6) is amended—

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

1 (2) in subsection (a)—

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

4 (B) by striking “that design, implement,
5 and evaluate” and inserting “to design, imple-
6 ment, and evaluate new or existing”;

7 (C) by striking “emergency care” and in-
8 serting “emergency medical”; and

9 (D) by inserting “, and improve access to
10 trauma care within such systems” before the
11 period;

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

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

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

18 “(C) a consortium of level I, II, or III
19 trauma centers designated by applicable State
20 or local agencies within an applicable State or
21 region, and, as applicable, other emergency
22 services providers; or

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

1 (4) in subsection (c)—

2 (A) in the matter preceding paragraph

3 (1)—

4 (i) by striking “that proposes a pilot
5 project”;

6 (ii) by striking “an emergency medical
7 and trauma system that—” and inserting
8 “a new or existing emergency medical and
9 trauma system. Such eligible entity shall
10 use amounts awarded under this sub-
11 section to carry out 2 or more of the fol-
12 lowing activities.”;

13 (B) in paragraph (1) —

14 (i) by striking “coordinates” and in-
15 sserting “Strengthening coordination and
16 communication”; and

17 (ii) by striking “an approach to emer-
18 gency medical and trauma system access
19 throughout the region, including 9–1–1
20 Public Safety Answering Points and emer-
21 gency medical dispatch;” and inserting
22 “approaches to improve situational aware-
23 ness and emergency medical and trauma
24 system access, including distribution of pa-

1 tients during a mass casualty incident,
2 throughout the region.”;

3 (C) in paragraph (2)—

4 (i) by striking “includes” and insert-
5 ing “Providing”;

6 (ii) by inserting “support patient
7 movement to” after “region to”; and

8 (iii) by striking the semicolon and in-
9 serting a period;

10 (D) in paragraph (3)—

11 (i) by striking “allows for” and insert-
12 ing “Improving”; and

13 (ii) by striking “; and” and inserting
14 a period;

15 (E) in paragraph (4), by striking “includes
16 a consistent” and inserting “Supporting a con-
17 sistent”; and

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

19 “(5) Establishing, implementing, and dissemi-
20 nating, or utilizing existing, as applicable, evidence-
21 based or evidence-informed practices across facilities
22 within such emergency medical and trauma system
23 to improve health outcomes, including such practices
24 related to management of injuries, and the ability of
25 such facilities to surge.

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

3 (5) in subsection (d)(2)—

4 (A) in subparagraph (A)—

5 (i) in the matter preceding clause (i),
6 by striking “the proposed” and inserting
7 “the applicable emergency medical and
8 trauma system”;

9 (ii) in clause (i), by inserting “or
10 Tribal entity” after “equivalent State of-
11 fice”; and

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

14 (B) by redesignating subparagraph (B) as
15 subparagraph (C); and

16 (C) by inserting after subparagraph (A)
17 the following:

18 “(B) for eligible entities described in sub-
19 paragraph (C) or (D) of subsection (b)(1), a de-
20 scription of, and evidence of, coordination with
21 the applicable State Office of Emergency Med-
22 ical Services (or equivalent State Office) or ap-
23 plicable such office for a Tribe or Tribal organi-
24 zation; and”;

25 (6) in subsection (e)—

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

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

4 **【“(3) WAIVER.—The Secretary may waive all**
5 or part of the matching requirement described in
6 paragraph (1) for any fiscal year for a State, con-
7 sortia of States, Indian Tribe or Tribal organization,
8 or trauma center, if the Secretary determines that
9 applying such matching requirement would result in
10 serious hardship or an inability to carry out the pur-
11 poses of the pilot program.”;】

12 (7) in subsection (f), by striking “population in
13 a medically underserved area” and inserting “medi-
14 cally underserved population”;

15 (8) in subsection (g)—

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

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

22 (C) by striking paragraph (4);

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

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

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

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

7 “(6) any evidence-based or evidence-informed
8 strategies developed or utilized pursuant to sub-
9 section (c)(5).”; and

10 (9) by amending subsection (h) to read as fol-
11 lows:

12 “(h) DISSEMINATION OF FINDINGS.—Not later than
13 1 year after the completion of the final project under sub-
14 section (a), the Secretary shall submit to the Committee
15 on Health, Education, Labor, and Pensions of the Senate
16 and the Committee on Energy and Commerce of the
17 House of Representatives a report describing the informa-
18 tion contained in each report submitted pursuant to sub-
19 section (g) and any additional actions planned by the Sec-
20 retary related to regionalized emergency care and trauma
21 systems.”.

22 (d) PROGRAM FUNDING.—Section 1232(a) of the
23 Public Health Service Act (42 U.S.C. 300d–32(a)) is
24 amended by striking “2010 through 2014” and inserting
25 “2023 through 2027”.

1 **SEC. 114. ASSESSMENT OF CONTAINMENT AND MITIGATION**
2 **OF INFECTIOUS DISEASES.**

3 (a) GAO STUDY.—The Comptroller General of the
4 United States shall conduct a study that reviews a sample
5 of States and territories that, in response to the COVID–
6 19 pandemic, implemented preparedness and response
7 plans that included isolation and quarantine recommenda-
8 tions or requirements. Such study shall include—

9 (1) a review of such State and territorial pre-
10 paredness and response plans in place during the
11 COVID–19 pandemic, an assessment of the extent
12 to which such plans facilitated or presented chal-
13 lenges to State and territorial responses to such
14 public health emergency, including response activi-
15 ties relating to isolation and quarantine to prevent
16 the spread of COVID–19; and

17 (2) a description of the technical assistance pro-
18 vided by the Federal Government to help States and
19 territories facilitate such activities during responses
20 to relevant public health emergencies declared by the
21 Secretary of Health and Human Services pursuant
22 to section 319 of the Public Health Service Act, in-
23 cluding the public health emergency with respect to
24 COVID–19, and a review of the degree to which
25 such State and territorial plans were implemented

1 and subsequently revised in response to the COVID–
2 19 pandemic to address any challenges.

3 (b) REPORT.—Not later than 1 year after the date
4 of enactment of this Act, the Comptroller General of the
5 United States shall submit a report on the study under
6 subsection (a) to the Committee on Health, Education,
7 Labor, and Pensions of the Senate and the Committee on
8 Energy and Commerce of the House of Representatives.

9 **TITLE II—IMPROVING PUBLIC**
10 **HEALTH PREPAREDNESS AND**
11 **RESPONSE CAPACITY**

12 **Subtitle A—Addressing Disparities**
13 **and Improving Public Health**
14 **Emergency Responses**

15 **SEC. 201. ADDRESSING SOCIAL DETERMINANTS OF HEALTH**
16 **AND IMPROVING HEALTH OUTCOMES.**

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

19 (1) by inserting after section 317U the fol-
20 lowing:

21 **“SEC. 317V. ADDRESSING SOCIAL DETERMINANTS OF**
22 **HEALTH AND IMPROVING HEALTH OUT-**
23 **COMES.**

24 “(a) IN GENERAL.—The Secretary shall, as appro-
25 priate, award grants, contracts, or cooperative agreements

1 to eligible entities for the conduct of evidence-based or evi-
2 dence-informed projects, which may include the develop-
3 ment of networks to improve health outcomes and reduce
4 health disparities by improving the capacity of such enti-
5 ties to address social determinants of health in commu-
6 nities.

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

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

18 “(B) be a consortia of entities described in sub-
19 paragraph (A);

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

23 “(3) in the case of an entity other than a com-
24 munity-based organization, demonstrate a history of

1 successfully working with an established community-
2 based organization to address health disparities;

3 “(4) submit a plan to conduct activities de-
4 scribed in subsection (a) based on a community
5 needs assessment that takes into account community
6 input; and

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

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

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

1 the support and use of public health and health care
2 professionals to address such social determinants of
3 health.

4 “(2) Establishing, maintaining, or improving, in
5 consultation with State, local, or Tribal health de-
6 partments, technology platforms or networks to sup-
7 port coordination among appropriate entities, and
8 providing information on health and related social
9 services, which may include activities to improve
10 data collection for public health purposes, in a man-
11 ner that is consistent with applicable Federal and
12 State privacy law.

13 “(3) Implementing best practices for improving
14 health outcomes and reducing disease among under-
15 served populations, including rural or racial and eth-
16 nic minority populations.

17 “(4) Supporting consideration of social deter-
18 minants of health in preparing for, and responding
19 to, public health emergencies, through outreach,
20 education, and other relevant activities.

21 “(d) BEST PRACTICES AND TECHNICAL ASSIST-
22 ANCE.—The Secretary, in consultation with the Director
23 of the Office of Minority Health, may award grants, con-
24 tracts, and cooperative agreements to public or nonprofit
25 private entities, including minority serving institutions as

1 described in section 371(a) of the Higher Education Act
2 of 1965, to—

3 “(1) identify or facilitate the development of
4 best practices to support improved health outcomes
5 and reduce health disparities by addressing social
6 determinants of health;

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

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

12 “(4) establish or operate regional centers to de-
13 velop, evaluate, and disseminate effective strategies
14 on the utilization of preventive health care services
15 to address social determinants of health, including
16 supporting research and training related to such
17 strategies.

18 “(e) AWARD PERIODS.—The Secretary shall issue
19 awards under this section for periods of not more than
20 5 years and may issue extensions of such award periods
21 for an additional period of up to 3 years.

22 “(f) REPORT.—Not later than September 30, 2026,
23 the Secretary shall submit to the Committee on Health,
24 Education, Labor, and Pensions of the Senate and the
25 Committee on Energy and Commerce of the House of

1 Representatives a report that includes information on ac-
2 tivities funded under this section. Such report shall in-
3 clude a description of—

4 “(1) changes in the capacity of public health
5 entities to address social determinants of health in
6 communities, including any applicable platforms or
7 networks developed or utilized to coordinate health
8 and related social services and any changes in work-
9 force capacity or capabilities;

10 “(2) improvements in health outcomes and in
11 reducing health disparities in medically underserved
12 communities;

13 “(3) activities conducted to support consider-
14 ation of social determinants of health in preparing
15 for, and responding to, public health emergencies,
16 through outreach, education, and other relevant ac-
17 tivities;

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

20 “(5) activities supported under subsection (e);
21 and

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

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

1 priated \$70,000,000 for each of fiscal years 2023 through
2 2027.”; and

3 (2) by striking section 330D (42 U.S.C. 254c–
4 4).

5 (b) GAO STUDY AND REPORT.—Not later than 4
6 years after the date of enactment of this Act, the Comp-
7 troller General of the United States shall submit to the
8 Committee on Health, Education, Labor, and Pensions of
9 the Senate and the Energy and Committee on Energy and
10 Commerce of the House of Representatives a report on
11 the program authorized under section 317V of the Public
12 Health Service Act, as added by subsection (a), including
13 a review of the outcomes and effectiveness of the program
14 and coordination with other programs in the Department
15 of Health and Human Services with similar goals to en-
16 sure that there was no unnecessary duplication of efforts.

17 **SEC. 202. NATIONAL ACADEMIES OF SCIENCES REPORT.**

18 (a) IN GENERAL.—Not later than 45 days after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services shall seek to enter into a contract with
21 the National Academies of Sciences, Engineering, and
22 Medicine (referred to in this section as the “Academies”)
23 to conduct a study to examine health disparities and the
24 effect of such disparities on health outcomes, which may

1 include health outcomes related to pandemic and other
2 public health emergencies.

3 (b) REPORT.—Pursuant to the contract under sub-
4 section (a), the Academies shall, not later than 2 years
5 after the date of enactment of this Act, issue a report in-
6 formed by the study conducted under such subsection that
7 includes—

8 (1) a review of previous recommendations made
9 by the Academies related to health disparities, in-
10 cluding in the report titled “Unequal Treatment:
11 Confronting Racial and Ethnic Disparities in
12 Healthcare”;

13 (2) identification of ways in which Federal poli-
14 cies have affected health disparities;

15 (3) strategies to improve health outcomes by re-
16 ducing health disparities, which may include edu-
17 cation and training; and

18 (4) an assessment of ongoing research and ac-
19 tivities to evaluate strategies to address health dis-
20 parities and address health outcomes, including ef-
21 fective service delivery models.

22 (c) CLARIFICATION.—In completing the requirements
23 of the contract under this section, the Academies may le-
24 verage relevant ongoing work of the Academies.

1 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated \$2,000,000 for fiscal year
3 2023 to carry out this section.

4 **Subtitle B—Improving Public**
5 **Health Data**

6 **SEC. 211. MODERNIZING BIOSURVEILLANCE CAPABILITIES**
7 **AND INFECTIOUS DISEASE DATA COLLEC-**
8 **TION.**

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

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

13 (2) in subsection (c)—

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

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

23 (C) in paragraph (5)—

24 (i) in subparagraph (A)—

1 (I) in the matter preceding clause
2 (i), by striking “and operating” and
3 inserting “, operating, and updating,
4 as appropriate,”;

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

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

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

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

19 (ii) in subparagraph (B)—

20 (I) in clause (i), by inserting
21 “and 180 days after the date of enact-
22 ment of the PREVENT Pandemics
23 Act,” after “Innovation Act of
24 2019,”;

1 (II) in clause (ii), by inserting
2 “experts in privacy and data secu-
3 rity;” after “forecasting);”; and

4 (III) in clause (iii)—

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

7 (bb) in subclause (VI), by
8 striking the period and inserting
9 a semicolon; and

10 (cc) by adding at the end
11 the following:

12 “(VII) strategies to integrate lab-
13 oratory and public health data sys-
14 tems and capabilities to support rapid
15 and accurate reporting of laboratory
16 test results and associated relevant
17 data;

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

1 “(IX) strategies to improve the
2 electronic exchange of health informa-
3 tion between State and local health
4 departments and health care providers
5 and facilities to improve public health
6 surveillance.”; and

7 (D) in paragraph (6)(A)—

8 (i) in the matter preceding clause (i),
9 by inserting “and every **[5]** years there-
10 after,” after “Innovation Act of 2019,”

11 (ii) in clause (iii)—

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

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

16 “(V) improve coordination and
17 collaboration, as appropriate, with
18 other Federal departments; and

19 “(VI) implement applicable les-
20 sons learned from recent public health
21 emergencies to address gaps in situa-
22 tional awareness and biosurveillance
23 capabilities;”;

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

1 (iv) in clause (v), by striking the pe-
2 riod and inserting “including a description
3 of how such steps will further the goals of
4 the network, consistent with paragraph
5 (1); and”; and

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

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

18 (3) in subsection (d)—

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

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

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

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

12 (4) by amending subsection (i) to read as fol-
13 lows:

14 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated—

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

18 “(2) to carry out subsections (b), (c), and (d),
19 \$136,800,000 for each of fiscal years 2022 and
20 2023.”; and

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

1 **SEC. 212. GENOMIC SEQUENCING, ANALYTICS, AND PUBLIC**
2 **HEALTH SURVEILLANCE OF PATHOGENS.**

3 (a) GUIDANCE SUPPORTING GENOMIC SEQUENCING
4 OF PATHOGENS COLLABORATION.—The Secretary of
5 Health and Human Services (referred to in this section
6 as the “Secretary”), in consultation with the heads of
7 other Federal departments or agencies, as appropriate,
8 shall issue guidance to support collaboration relating to
9 genomic sequencing of pathogens, including the use of new
10 and innovative approaches and technology for the detec-
11 tion, characterization, and sequencing of pathogens, to im-
12 prove public health surveillance and preparedness and re-
13 sponse activities, consistent with section 2824 of the Pub-
14 lic Health Service Act, as added by subsection (b). Such
15 guidance shall address the secure sharing, for public
16 health surveillance purposes, of specimens of such patho-
17 gens, between appropriate entities and public health au-
18 thorities pursuant to the regulations promulgated under
19 section 264(c) of the Health Insurance Portability and Ac-
20 countability Act of 1996 (42 U.S.C. 1320d–2 note), in a
21 manner that protects personal privacy to the extent re-
22 quired by applicable privacy law, at a minimum, and the
23 appropriate use of sequence data derived from such speci-
24 mens.

25 (b) GENOMIC SEQUENCING PROGRAM.—Title
26 XXVIII of the Public Health Service Act (42 U.S.C.

1 300hh et seq.) is amended by adding at the end the fol-
2 lowing

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

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

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

20 “(A) identify and respond to emerging in-
21 fectious disease threats; and

22 “(B) identify the potential use of genomic
23 sequencing technologies, advanced computing,
24 and other advanced technology to inform sur-
25 veillance activities and incorporate the use of

1 such technologies, as appropriate, into related
2 activities;

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

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

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

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

1 “(c) CENTERS OF EXCELLENCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(I) electronic case reporting;

11 “(II) syndromic surveillance;

12 “(III) reporting of vital statistics;

13 and

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

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

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

23 “(C) NO DUPLICATIVE EFFORTS.—

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

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

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

15 (b) STUDY ON LABORATORY INFORMATION STAND-
16 ARDS.—

17 (1) IN GENERAL.—Not later than 1 year after
18 the date of enactment of this Act, the Office of the
19 National Coordinator for Health Information Tech-
20 nology shall conduct a study to review the use of
21 standards for electronic ordering and reporting of
22 laboratory test results.

23 (2) AREAS OF CONCENTRATION.—In conducting
24 the study under paragraph (1), the Office of the Na-

1 tional Coordinator for Health Information Tech-
2 nology shall—

3 (A) determine the extent to which clinical
4 laboratories are using standards for electronic
5 ordering and reporting of laboratory test re-
6 sults;

7 (B) assess trends in laboratory compliance
8 with standards for ordering and reporting lab-
9 oratory test results and the effect of such
10 trends on the interoperability of laboratory data
11 with public health data systems;

12 (C) identify challenges related to collection
13 and reporting of demographic and other data
14 elements with respect to laboratory test results;

15 (D) identify any challenges associated with
16 using or complying with standards and report-
17 ing laboratory test results with data elements
18 identified in standards for electronic ordering
19 and reporting of such results; and

20 (E) review other relevant areas determined
21 appropriate by the Office of the National Coor-
22 dinator for Health Information Technology.

23 (3) REPORT.—Not later than 2 years after the
24 date of enactment of this Act, the Office of the Na-
25 tional Coordinator for Health Information Tech-

1 nology shall submit to the Committee on Health,
2 Education, Labor, and Pensions of the Senate and
3 the Committee on Energy and Commerce of the
4 House of Representatives a report concerning the
5 findings of the study conducted under paragraph
6 (1).

7 (c) SUPPORTING INFORMATION SHARING THROUGH
8 DATA USE AGREEMENTS.—

9 (1) INTERAGENCY DATA USE AGREEMENTS
10 WITHIN THE DEPARTMENT OF HEALTH AND HUMAN
11 SERVICES FOR PUBLIC HEALTH EMERGENCIES.—

12 (A) IN GENERAL.—The Secretary of
13 Health and Human Services (referred to in this
14 subsection as the “Secretary”) shall, as appro-
15 priate, facilitate the development of, or updates
16 to, memoranda of understanding, data use
17 agreements, or other applicable interagency
18 agreements regarding appropriate access, ex-
19 change, and use of public health data between
20 the Centers for Disease Control and Prevention,
21 the Office of the Assistant Secretary for Pre-
22 paredness and Response, and other relevant
23 agencies or offices within the Department of
24 Health and Human Services in order to prepare

1 for, identify, monitor, and respond to, declared
2 or potential public health emergencies.

3 (B) REQUIREMENTS.—In carrying out ac-
4 tivities pursuant to subparagraph (A), the Sec-
5 retary shall—

6 (i) ensure that the agreements and
7 memoranda of understanding described in
8 such subparagraph—

9 (I) address the methods of grant-
10 ing access to data held by one agency
11 or office with another to support the
12 respective missions of such agencies
13 or offices;

14 (II) consider minimum necessary
15 principles of data sharing for appro-
16 priate use;

17 (III) include appropriate privacy
18 and cybersecurity protections; and

19 (IV) are subject to regular up-
20 dates, as appropriate;

21 (ii) collaborate with the Centers for
22 Disease Control and Prevention, the Office
23 of the Assistant Secretary for Prepared-
24 ness and Response, the Office of the Chief
25 Information Officer, and, as appropriate,

1 the Office of the National Coordinator for
2 Health Information Technology, and other
3 entities within the Department of Health
4 and Human Services; and

5 (iii) consider the terms [and condi-
6 tions] of any existing data use agreements
7 with other public or private entities and
8 any need for updates to such existing
9 agreements, consistent with paragraph (2).

10 (2) DATA USE AGREEMENTS WITH EXTERNAL
11 ENTITIES.—The Secretary, acting through the Di-
12 rector of the Centers for Disease Control and Pre-
13 vention and the Assistant Secretary for Prepared-
14 ness and Response, may update memoranda of un-
15 derstanding, data use agreements, or other applica-
16 ble agreements and contracts to improve appropriate
17 access, exchange, and use of public health data be-
18 tween the Centers for Disease Control and Preven-
19 tion and the Office of the Assistant Secretary for
20 Preparedness and Response and external entities, in-
21 cluding State health departments, laboratories, hos-
22 pitals, electronic health records vendors, and other
23 entities, as applicable and appropriate, in order to
24 prepare for, identify, monitor, and respond to de-
25 clared or potential public health emergencies.

1 “(3) State, local, and Tribal health depart-
2 ments.

3 “(b) CONTENT, FORM, AND MANNER.—The Sec-
4 retary shall, consistent with the requirements of this sec-
5 tion, work with such officials and relevant stakeholders to
6 provide information on the content, form, and manner in
7 which such data may most effectively support the ability
8 of State, local, and Tribal health departments to respond
9 to such communicable diseases.

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

16 “(d) EXEMPTION OF CERTAIN PUBLIC HEALTH
17 DATA FROM DISCLOSURE.—The Secretary, acting
18 through the Director of the Centers for Disease Control
19 and Prevention, may exempt from disclosure under section
20 552(b)(3) of title 5, United States Code, public health
21 data that are gathered under this section if—

22 “(1) an individual is identified through such
23 data; or

24 “(2) there is at least a very small risk, as deter-
25 mined by current scientific practices or statistical

1 methods, that some combination of the information,
2 the request, and other available data sources or the
3 application of technology could be used to deduce
4 the identity of an individual.”.

5 (e) IMPROVING PUBLIC HEALTH DATA COLLEC-
6 TION.—

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

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

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

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

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

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

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

21 (B) developing or identifying methods to
22 improve communication with patients, including
23 to better capture information related to demo-
24 graphics of such individuals;

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

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

8 (E) other activities, as the Secretary deter-
9 mines appropriate.

10 (4) REPORTING.—

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

16 (B) REPORT TO CONGRESS.—Not later
17 than **[X]** months after the completion of the
18 program under this subsection, the Secretary
19 shall submit a report to Congress on the suc-
20 cess of best practices developed under such pro-
21 gram, opportunities for further dissemination of
22 such best practices, and recommendations for
23 improving the capture, access, exchange, and
24 use of information to improve public health and
25 reduce health disparities.

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

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

9 **SEC. 214. EPIDEMIC FORECASTING AND OUTBREAK ANA-**
10 **LYTICS.**

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

14 **“SEC. 2825. EPIDEMIC FORECASTING AND OUTBREAK ANA-**
15 **LYTICS.**

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

1 puate, the capabilities to public and private entities, which
2 may include conducting such activities through collabo-
3 rative partnerships with public and private entities, includ-
4 ing academic institutions, and other Federal agencies, con-
5 sistent with section 319D, as applicable.

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

13 “(c) ANNUAL REPORTS.—Not later than 1 year after
14 the date of enactment of this section, and annually there-
15 after for each of the subsequent 4 years, the Secretary
16 shall prepare and submit 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, regarding an update on progress on
20 activities conducted under this section to develop infec-
21 tious disease outbreak analysis capabilities and any addi-
22 tional information relevant to such efforts.”.

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

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

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

8 (1) in subsection (a)—

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

12 (B) by striking “Federal,”;

13 (2) in subsection (b)—

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

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

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

4 (3) in subsection (c)(2)—

5 (A) by striking “Federal,”; and

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

10 (4) in subsection (d)—

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

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

22 (B) in paragraph (2)—

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

25 “(A) IN GENERAL.—For each year”;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (C) recommended steps to improve hiring,
6 recruitment, and retention of the public health
7 workforce; and

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

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

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

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

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

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

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

10 (3) in subsection (b)—

11 (A) in the matter preceding paragraph

12 (1)—

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

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

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

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

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

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

8 “(A) health conditions prevalent in—

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

13 “(ii) other such populations or geo-
14 graphic areas that may require additional
15 support during public health emergencies,
16 which may include counties identified by
17 the Secretary using applicable measures
18 developed by the Centers for Disease Con-
19 trol and Prevention or other Federal agen-
20 cies; and

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

24 “(i) promoting awareness of services
25 and resources to increase access to health

1 care, mental health services, child services,
2 technology, housing services, educational
3 services, nutrition services, employment
4 services, and other services; and

5 “(ii) assisting in conducting individual
6 and community needs assessments;

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

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

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

14 (i) by striking “to identify” and in-
15 serting “identify”;

16 (ii) by striking “healthcare agencies”
17 and inserting “health care agencies”; and

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

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

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

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

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

16 (5) in subsection (d)—

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

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

21 “(1) propose to serve—

22 “(A) areas with populations that have a
23 high rate of chronic disease, infant mortality, or
24 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; or” 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.”;

1 (6) in subsection (e)—

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

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

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

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

21 “(g) DISSEMINATION OF BEST PRACTICES.—Not
22 later than 4 years after the date of enactment of the PRE-
23 VENT Pandemics Act, the Secretary shall, based on ac-
24 tivities carried out under this section and in consultation
25 with relevant stakeholders, identify and disseminate evi-

1 dence-based or evidence-informed practices regarding re-
2 cruitment and retention of community health workers and
3 paraprofessionals to address ongoing public health and
4 community health needs, and to prepare for, and respond
5 to, future public health emergencies.

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

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

22 (8) by redesignating subsection (k) as sub-
23 section (j); and

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

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

3 (B) by redesignating paragraph (3) as
4 paragraph (1);

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

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

13 (ii) by striking “as defined in section
14 1861(aa) of the Social Security Act))” and
15 inserting “(as described in section
16 1861(aa)(4)(B) of the Social Security
17 Act)”; and

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

19 “(2) INDIAN TRIBE; TRIBAL ORGANIZATION.—
20 The terms ‘Indian Tribe’ and ‘Tribal organization’
21 have the meanings given the terms ‘Indian tribe’ and
22 ‘tribal organization’, respectively, in section 4 of the
23 Indian Self-Determination and Education Assistance
24 Act.

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

5 (b) GAO STUDY AND REPORT.—Not later than 4
6 years after the date of enactment of this Act, the Comp-
7 troller General of the United States shall submit to the
8 Committee on Health, Education, Labor, and Pensions of
9 the Senate and the Committee on Energy and Commerce
10 of the House of Representatives a report on the program
11 authorized under section 399V of the Public Health Serv-
12 ice Act (42 U.S.C. 280g–11) (as amended by subsection
13 (a)), including a review of the outcomes and effectiveness
14 of the program and coordination with applicable programs
15 of the Health Resources and Services Administration to
16 ensure there is no unnecessary duplication of efforts
17 among such programs.

18 **SEC. 223. IMPROVING PUBLIC HEALTH EMERGENCY RE-**
19 **SPONSE CAPACITY.**

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

24 “(g) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC
25 HEALTH EMERGENCY RESPONSES.—

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

10 “(A) address a critical hiring need directly
11 related to responding to a public health emer-
12 gency declared by the Secretary under this sec-
13 tion; or

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

20 “(2) NUMBER OF APPOINTMENTS.—Each fiscal
21 year in which the Secretary makes a determination
22 of a public health emergency under subsection (a)
23 (not including a renewal), the Secretary may directly
24 appoint not more than—

1 “(A) **【200】** individuals under paragraph
2 (1)(A); and

3 “(B) **【50】** individuals under paragraph
4 (1)(B).

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

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

13 “(A) the number of positions filled through
14 such authority;

15 “(B) the types of appointments of such po-
16 sitions;

17 “(C) the titles, occupational series, and
18 grades of such positions;

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

21 “(E) the number of qualified applicants
22 who apply for such positions;

23 “(F) the qualification criteria for such po-
24 sitions; and

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

3 “(5) NOTIFICATION TO CONGRESS.—In the
4 event the Secretary, within a single fiscal year, [di-
5 rectly appoints more than 75 percent of the individ-
6 uals allowable under either subparagraph (A) or (B)
7 of paragraph (2),] the Secretary shall, not later
8 than [15] days after the date of such action, notify
9 the Committee on Health, Education, Labor, and
10 Pensions of the Senate and the Committee on En-
11 ergy and Commerce of the House of Representa-
12 tives. Such notification shall, in a manner that pro-
13 tects personal privacy, to the extent required by ap-
14 plicable Federal and State privacy law, at a min-
15 imum, include—

16 “(A) information on each such appoint-
17 ment within such fiscal year;

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

21 “(C) the additional number of personnel, if
22 any, the Secretary anticipates to be necessary
23 to adequately support a response to a public
24 health emergency declared under this section

1 using the authorities described in paragraph (1)
2 within such fiscal year.

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

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

17 (b) GAO REPORT.—Not later than 2 years after the
18 date of enactment of this Act, and again 180 days after
19 the date on which the authority provided under section
20 319(g) of the Public Health Service Act (42 U.S.C.
21 247d(g)) expires pursuant to paragraph (7) of such sec-
22 tion, the Comptroller General of the United States shall
23 submit to the Committee on Health, Education, Labor,
24 and Pensions of the Senate and the Committee on Energy
25 and Commerce of the House of Representatives a report

1 on the use of the authority provided under such section.
2 Such report shall, in a manner that protects personal pri-
3 vacy, to the extent required by applicable Federal and
4 State privacy law, at a minimum, include information
5 on—

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

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

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

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

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

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

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

24 (8) any challenges, limitations, or gaps related
25 to the use of the authority under each such subpara-

1 graph and any related recommendations to address
2 such challenges, limitations, or gaps.

3 **SEC. 224. EXTENSION OF AUTHORITIES TO SUPPORT**
4 **HEALTH PROFESSIONAL VOLUNTEERS AT**
5 **COMMUNITY HEALTH CENTERS.**

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

8 **Subtitle D—Improving Public**
9 **Health Responses**

10 **SEC. 231. CENTERS FOR PUBLIC HEALTH PREPAREDNESS**
11 **AND RESPONSE.**

12 (a) IN GENERAL.—Section 319F of the Public
13 Health Service Act (42 U.S.C. 247d-6) is amended—

14 (1) by striking subsection (d) and inserting the
15 following:

16 “(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS
17 AND RESPONSE.—

18 “(1) IN GENERAL.—The Secretary, acting
19 through the Director of the Centers for Disease
20 Control and Prevention, may award grants, con-
21 tracts, or cooperative agreements to institutions of
22 higher education, including accredited schools of
23 public health, or other nonprofit private entities to
24 establish or support a network of Centers for Public

1 Health Preparedness and Response (referred to in
2 this subsection as ‘Centers’).

3 “(2) ELIGIBILITY.—To be eligible to receive an
4 award under this subsection, an entity shall submit
5 to the Secretary an application containing such in-
6 formation as the Secretary may require, including a
7 description of how the entity will—

8 “(A) coordinate relevant activities with
9 State, local, and Tribal health departments and
10 officials, health care facilities, and health care
11 coalitions to improve public health preparedness
12 and response, as informed by the public health
13 preparedness and response needs of the commu-
14 nity, or communities, involved;

15 “(B) prioritize efforts to implement evi-
16 dence-informed or evidence-based practices to
17 improve public health preparedness and re-
18 sponse, including by helping to reduce the
19 transmission of emerging infectious diseases;
20 and

21 “(C) use funds awarded under this sub-
22 section, including by carrying out any activities
23 described in paragraph (3).

24 “(3) USE OF FUNDS.—As a condition of receiv-
25 ing funds under this subsection, Centers established

1 or supported shall carry out activities to advance
2 public health preparedness and response capabilities,
3 which may include by—

4 “(A) identifying, translating, and dissemi-
5 nating promising research findings or strategies
6 into evidence-informed or evidence-based prac-
7 tices to inform preparedness for, and responses
8 to, chemical, biological, radiological, or nuclear
9 threats, including emerging infectious diseases,
10 and other public health emergencies, which may
11 include conducting research related to public
12 health preparedness and response systems;

13 “(B) improving awareness of such evi-
14 dence-informed or evidence-based practices and
15 other relevant scientific or public health infor-
16 mation among health care professionals, public
17 health professionals, other stakeholders, and the
18 public, including through the development, eval-
19 uation, and dissemination of trainings and
20 training materials, consistent with section
21 2802(b)(2), as applicable and appropriate, to
22 support preparedness for, and responses to,
23 such threats;

24 “(C) utilizing and expanding relevant tech-
25 nological and analytical capabilities to inform

1 public health and medical preparedness and re-
2 sponse efforts;

3 “(D) expanding activities, including
4 through public-private partnerships, related to
5 public health preparedness and response, in-
6 cluding participation in drills and exercises and
7 training public health experts, as appropriate;
8 and

9 “(E) providing technical assistance and ex-
10 pertise related to responses to public health
11 emergencies, as appropriate, to State, local, and
12 Tribal health departments and other entities
13 pursuant to paragraph (2)(A).

14 “(4) DISTRIBUTION OF AWARDS.—In awarding
15 grants, contracts, or cooperative agreements under
16 this subsection, the Secretary shall support not
17 fewer than 10 Centers, subject to the availability of
18 appropriations, and ensure that such awards are eq-
19 uitably distributed among the geographical regions
20 of the United States.”; and

21 (2) in subsection (f)(1)(C), by striking “, of
22 which \$5,000,000 shall be used to carry out para-
23 graphs (3) through (5) of such subsection”.

24 (b) REPEAL.—Section 319G of the Public Health
25 Service Act (42 U.S.C. 247d-7) is repealed.

1 **SEC. 232. VACCINE DISTRIBUTION PLANS.**

2 Section 319A of the Public Health Service Act (42
3 U.S.C. 247d-1) is amended—

4 (1) in subsection (a)—

5 (A) by inserting “, or other federally pur-
6 chased vaccine to address another pandemic”
7 before the period at the end of the first sen-
8 tence; and

9 (B) by inserting “or other pandemic” be-
10 fore the period at the end of the second sen-
11 tence; and

12 (2) in subsection (d), by inserting “or other
13 pandemics” after “influenza pandemics”.

14 **TITLE III—ACCELERATING RE-**
15 **SEARCH AND COUNTER-**
16 **MEASURE DISCOVERY**

17 **SEC. 301. RESEARCH AND ACTIVITIES RELATED TO LONG-**
18 **TERM HEALTH EFFECTS OF SARS-COV-2 IN-**
19 **FECTION.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services shall, as appropriate—

22 (1) continue to conduct or support basic, clin-
23 ical, epidemiological, behavioral, and translational
24 research and public health surveillance related to the
25 pathogenesis, prevention, diagnosis, and treatment

1 of the long-term health effects of SARS-CoV-2 in-
2 fection; and

3 (2) in consultation with health professional as-
4 sociations, researchers, and other relevant experts,
5 develop and inform recommendations, guidance, and
6 provide educational materials for health care pro-
7 viders and the general public on the long-term ef-
8 fects of SARS-CoV-2 infection, consistent with the
9 findings of studies and research under paragraph
10 (1).

11 (b) ANNUAL REPORTS.—Not later than 1 year after
12 the date of enactment of this Act, and annually thereafter
13 for the next 4 years, the Secretary of Health and Human
14 Services shall prepare and submit a report to the Com-
15 mittee on Health, Education, Labor, and Pensions of the
16 Senate and the Committee on Energy and Commerce of
17 the House of Representatives regarding an overview of the
18 research conducted or supported under this section and
19 any relevant findings. Such reports may include informa-
20 tion about how the research and relevant findings under
21 this section relate to other research efforts supported by
22 other public or private entities.

1 **SEC. 302. RESEARCH CENTERS FOR PATHOGENS OF PAN-**
2 **DEMIC CONCERN.**

3 Subpart 6 of part C of title IV of the Public Health
4 Service Act is amended by inserting after section 447C
5 (42 U.S.C. 285f-4) the following:

6 **“SEC. 447D. RESEARCH CENTERS FOR PATHOGENS OF PAN-**
7 **DEMIC CONCERN.**

8 “(a) IN GENERAL.—The Director of the Institute, in
9 collaboration, as appropriate, with the directors of applica-
10 ble institutes, centers, and divisions of the National Insti-
11 tutes of Health, the Assistant Secretary for Preparedness
12 and Response, and the Director of the Biomedical Ad-
13 vanced Research and Development Authority, shall estab-
14 lish or continue a multidisciplinary research program to
15 advance the discovery and preclinical development of med-
16 ical products for priority virus families and other viral
17 pathogens with a significant potential to cause a pan-
18 demic, through support for research centers.

19 “(b) USES OF FUNDS.—The Director of the Institute
20 shall award funding through grants, contracts, or coopera-
21 tive agreements to public or private entities to provide
22 support for research centers described in subsection (a)
23 for the purpose of—

24 “(1) conducting basic research through pre-
25 clinical development of new medical products or

1 technologies, including platform technologies, to ad-
2 dress pathogens of pandemic concern;

3 “(2) identifying potential targets for thera-
4 peutic candidates, including antivirals, to treat such
5 pathogens;

6 “(3) identifying existing medical products with
7 the potential to address such pathogens, including
8 candidates that could be used in outpatient settings;
9 and

10 “(4) carrying out or supporting other research
11 related to medical products to address such patho-
12 gens, as determined appropriate by the Director.

13 “(c) COORDINATION.—The Director of the Institute
14 shall, as appropriate, provide for the coordination of ac-
15 tivities among the centers described in subsection (a), in-
16 cluding through—

17 “(1) facilitating the exchange of information
18 and regular communication among the centers, as
19 appropriate; and

20 “(2) requiring the periodic preparation and sub-
21 mission to the Director of reports on the activities
22 of each center.

23 “(d) PRIORITY.—In awarding funding through
24 grants, contracts, or cooperative agreements under sub-
25 section (a), the Director of the Institute shall, as appro-

1 puate, give priority to applicants with existing frameworks
2 and partnerships, as applicable, to support the advance-
3 ment of such research.

4 “(e) COLLABORATION.—The Director of the Institute
5 shall—

6 “(1) collaborate with the heads of other appro-
7 priate Federal departments, agencies, and offices
8 with respect to the identification of additional pri-
9 ority virus families and other viral pathogens with a
10 significant potential to cause a pandemic; and

11 “(2) collaborate with the Director of the Bio-
12 medical Advanced Research and Development Au-
13 thority with respect to the research conducted by
14 centers described in subsection (a), including, as ap-
15 propriate, providing any updates on the research ad-
16 vancements made by such centers, identifying any
17 advanced research and development needs for such
18 countermeasures, consistent with section
19 319L(a)(6), and taking into consideration existing
20 manufacturing capacity and future capacity needs
21 for such medical products or technologies, including
22 platform technologies, supported by the centers de-
23 scribed in subsection (a).

24 “(f) SUPPLEMENT, NOT SUPPLANT.—Any support
25 received by a center described in subsection (a) under this

1 section shall be used to supplement, and not supplant,
2 other public or private support for activities authorized to
3 be supported.”.

4 **SEC. 303. IMPROVING MEDICAL COUNTERMEASURE RE-**
5 **SEARCH COORDINATION.**

6 Section 402(b) in the Public Health Service Act (42
7 U.S.C. 282(b)) is amended—

8 (1) in paragraph (24), by striking “and” at the
9 end;

10 (2) in paragraph (25), by striking the period
11 and inserting “; and”; and

12 (3) by inserting after paragraph (25) the fol-
13 lowing:

14 “(26) shall consult with the Assistant Secretary
15 for Preparedness and Response, the Director of the
16 Biomedical Advanced Research and Development
17 Authority, the Director of the Centers for Disease
18 Control and Prevention, and the heads of other Fed-
19 eral agencies and offices, as appropriate, regarding
20 research needs to advance medical countermeasures
21 to diagnose, mitigate, prevent, or treat harm from
22 any biological agent or toxin, including emerging in-
23 fectious diseases, chemical, radiological, or nuclear
24 agent that may cause a public health emergency or

1 other research needs related to emerging public
2 health threats.”.

3 **SEC. 304. ACCESSING SPECIMEN SAMPLES AND DIAG-**
4 **NOSTIC TESTS.**

5 (a) IMPROVING RESEARCH AND DEVELOPMENT OF
6 MEDICAL COUNTERMEASURES FOR NOVEL PATHO-
7 GENS.—

8 (1) SAMPLE ACCESS.—Not later than 1 year
9 after the date of enactment of this Act, the Sec-
10 retary of Health and Human Services (referred to in
11 this subsection as the “Secretary”) shall make pub-
12 licly available policies and procedures related to pub-
13 lic and private entities accessing specimens of, or
14 specimens containing, pathogens or suitable surro-
15 gates for, or alternatives to, such pathogens as the
16 Secretary determines appropriate to support public
17 health preparedness and response activities or bio-
18 medical research for purposes of the development
19 and validation, as applicable, of medical products to
20 address emerging infectious diseases and for use to
21 otherwise respond to emerging infectious diseases.
22 Such policies and procedures shall take into account,
23 as appropriate, any applicable existing Federal re-
24 sources.

1 (2) GUIDANCE.—The Secretary shall issue
2 guidance regarding the procedures for carrying out
3 paragraph (1), including—

4 (A) the method for requesting such sam-
5 ples;

6 (B) considerations for sample availability
7 and use of suitable surrogates or alternatives to
8 such pathogens, as appropriate, including appli-
9 cable safeguard and security measures; and

10 (C) information required to be provided in
11 order to receive such samples or suitable surro-
12 gates or alternatives.

13 (b) EARLIER DEVELOPMENT OF DIAGNOSTIC
14 TESTS.—Title III of the Public Health Service Act is
15 amended by inserting after section 319A (42 U.S.C.
16 247d–1) the following:

17 **“SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC**
18 **TESTS.**

19 “The Secretary may contract with public and private
20 entities, as appropriate, to increase capacity in the rapid
21 development, validation, manufacture, and dissemination
22 of diagnostic tests, as appropriate, to State, local, and
23 Tribal health departments and other appropriate entities
24 for immediate public health response activities to address
25 an emerging infectious disease with respect to which a

1 public health emergency is declared under section 319, or
2 that has significant potential to cause such a public health
3 emergency.”.

4 **TITLE IV—MODERNIZING AND**
5 **STRENGTHENING THE SUP-**
6 **PLY CHAIN FOR VITAL MED-**
7 **ICAL PRODUCTS**

8 **SEC. 401. WARM BASE MANUFACTURING CAPACITY FOR**
9 **MEDICAL COUNTERMEASURES.**

10 (a) IN GENERAL.—Section 319L of the Public
11 Health Service Act (42 U.S.C. 247d–7e) is amended—

12 (1) in subsection (a)(6)(B)—

13 (A) by redesignating clauses (iv) and (v) as
14 clauses (v) and (vi), respectively;

15 (B) by inserting after clause (iii), the fol-
16 lowing:

17 “(iv) activities to support, maintain,
18 and improve domestic manufacturing surge
19 capacity and capabilities, as appropriate,
20 including through the utilization of ad-
21 vanced manufacturing and platform tech-
22 nologies, to increase the availability of
23 products that are or may become qualified
24 countermeasures or qualified pandemic or
25 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 regarding the avail-
19 ability of countermeasures and the mainte-
20 nance of domestic manufacturing surge ca-
21 pacity and capabilities, including any
22 planned uses of such capacity and capabili-
23 ties in the near- and mid-term, and identi-
24 fication of any significant challenges re-

1 lated to the long-term maintenance of such
2 capacity and capabilities; 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 Subparagraph (D) of section 319F-2(a)(3) of the
10 Public Health Service Act (42 U.S.C. 247d-6b(a)(3)) is
11 amended to read as follows:

12 “(D) review and revise, as appropriate, the
13 contents of the stockpile on a regular basis to
14 ensure that—

15 “(i) emerging threats, advanced tech-
16 nologies, and new countermeasures are
17 adequately considered;

18 “(ii) the potential depletion of coun-
19 termeasures currently in the stockpile is
20 identified and appropriately addressed, in-
21 cluding through necessary replenishment;
22 and

23 “(iii) such contents are in working
24 condition or usable, as applicable, and are
25 ready for deployment, which may include

1 conducting maintenance services on such
2 contents of the stockpile and disposing of
3 such contents that are no longer in work-
4 ing condition, or usable, as applicable;”.

5 **SEC. 404. IMPROVING TRANSPARENCY AND PREDICT-**
6 **ABILITY OF PROCESSES OF THE STRATEGIC**
7 **NATIONAL STOCKPILE.**

8 (a) GUIDANCE.—Not later than **[60]** days after the
9 date of enactment of this Act, the Secretary of Health and
10 Human Services (referred to in this section as the “Sec-
11 retary”) shall issue guidance describing the processes by
12 which the Secretary deploys the contents of the Strategic
13 National Stockpile under section 319F–2(a) of the Public
14 Health Service Act (42 U.S.C. 247d–6b(a)), or otherwise
15 distributes medical countermeasures, as applicable, to
16 States, territories, Indian Tribes and Tribal organizations
17 (as such terms are defined under section 4 of the Indian
18 Self-Determination and Education Assistance Act), and
19 other applicable entities. Such guidance shall include in-
20 formation related to processes by which to request access
21 to the contents of the Strategic National Stockpile, factors
22 considered by the Secretary when making deployment or
23 distribution decisions, and processes and points of contact
24 through which entities may contact the Secretary to ad-
25 dress any issues related to products requested or received

1 by such entity from the stockpile, and on other relevant
2 topics.

3 (b) ANNUAL MEETINGS.—Section 319F–2(a)(3) of
4 the Public Health Service Act (42 U.S.C. 247d–6b(a)(3))
5 is amended—

6 (1) in subparagraph (J), by striking the period
7 at the end and inserting “; and”; and

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

9 “(K) convene meetings, not less than once
10 per year, with representatives from State, local,
11 and Tribal health departments or officials, rel-
12 evant industries, other Federal agencies, and
13 other appropriate stakeholders, in a manner
14 that does not compromise national security, to
15 coordinate and share information related to
16 maintenance and use of the stockpile, including
17 a description of future countermeasure needs
18 and additions, modifications, and replenish-
19 ments of the contents of the stockpile, and con-
20 siderations related to the manufacturing and
21 procurement of products consistent with the re-
22 quirements of the Buy American Act of 1933,
23 as appropriate.”.

1 **SEC. 405. IMPROVING SUPPLY CHAIN FLEXIBILITY FOR THE**
2 **STRATEGIC NATIONAL STOCKPILE.**

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

5 (1) in subsection (a)—

6 **[(A) in paragraph (3)(F), by striking “as**
7 **required by the Secretary of Homeland Secu-**
8 **urity” and inserting “at the discretion of the**
9 **Secretary, in consultation with, or at the re-**
10 **quest of, the Secretary of Homeland Secu-**
11 **urity,”;]**

12 (B) by redesignating paragraphs (5) and
13 (6) as paragraphs (7) and (8), respectively;

14 (C) by inserting after paragraph (4) the
15 following:

16 “(5) **VENDOR-MANAGED SURGE CAPACITY.**—

17 “(A) **IN GENERAL.**—For the purposes of
18 maintaining the stockpile under paragraph (1)
19 and carrying out procedures under paragraph
20 (3), the Secretary may enter into contracts
21 **【through a competitive process】** or cooperative
22 agreements with vendors, which may include
23 manufacturers or distributors of medical prod-
24 ucts, with respect to medical products intended
25 to be delivered to the ownership of the Federal
26 Government. Each such contract or cooperative

1 agreement shall be subject to such terms and
2 conditions as the Secretary may specify, includ-
3 ing terms and conditions with respect to—

4 “(i) procurement, maintenance, stor-
5 age, and delivery of reserve amounts of
6 products under such contract or coopera-
7 tive agreement, which may consider, as ap-
8 propriate, costs of transporting and han-
9 dling such products; and

10 “(ii) maintenance of domestic manu-
11 facturing capacity and capabilities of such
12 products to ensure additional reserved pro-
13 duction capacity and capabilities are avail-
14 able, and that such capacity and capabili-
15 ties are able to support the rapid manufac-
16 ture, purchase, and delivery of such prod-
17 ucts, as required by the Secretary to pre-
18 pare for, or respond to, an existing or po-
19 tential public health emergency.

20 “(B) REPORT.—Not later than **[2 years]**
21 after the date of enactment of the PREVENT
22 Pandemics Act, and annually thereafter, the
23 Secretary shall submit to the Committee on
24 Health, Education, Labor, and Pensions of the
25 Senate and the Committee on Energy and Com-

1 merce of the House of Representatives a report
2 on any contracts or cooperative agreements en-
3 tered into under subparagraph (A) for purposes
4 of establishing and maintaining vendor-man-
5 aged inventory or reserve manufacturing capac-
6 ity and capabilities for products intended for
7 the stockpile, including a description of—

8 “(i) the amount of each award;

9 “(ii) the recipient of each award;

10 “(iii) the product or products covered
11 through each award; and

12 “(iv) how the Secretary works with
13 each recipient to ensure situational aware-
14 ness related to the manufacturing capacity
15 for, or inventory of, such products and co-
16 ordinates the distribution and deployment
17 of such products, as appropriate and appli-
18 cable.”; and

19 (D) in subparagraph (A) of paragraph (7),
20 as so redesignated—

21 (i) in clause (viii), by striking “; and”
22 and inserting a semicolon;

23 (ii) in clause (ix), by striking the pe-
24 riod and inserting “; and”; and

1 (iii) by adding at the end the fol-
2 lowing:

3 “(x) an assessment of any contracts
4 or cooperative agreements entered into
5 pursuant to paragraph (5).”; and

6 (2) in subsection (c)(2)(C), by striking “on an
7 annual basis” and inserting “not later than March
8 15 of each year”.

9 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
10 319F–2(f)(1) of the Public Health Service Act (42 U.S.C.
11 247d–6b(f)(1)) is amended by striking “\$610,000,000 for
12 each of fiscal years 2019 through 2023” and inserting
13 “\$610,000,000 for each of fiscal year 2019 through 2021,
14 and \$750,000,000 for each of fiscal years 2022 and
15 2023”.

16 **SEC. 406. STRATEGIC NATIONAL STOCKPILE CONTRACT DU-**
17 **RATION.**

18 (a) IN GENERAL.—Section 319F–2(a) of the Public
19 Health Service Act is amended by inserting after para-
20 graph (5), as added by section **【405(a)(1)(C)】**, the fol-
21 lowing:

22 “(6) CONTRACT DURATION.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graphs (B) and (C), the Secretary, in maintain-
25 ing the stockpile under paragraph (1) and car-

1 rying out procedures under paragraph (3) con-
2 sistent with the requirements of the Federal Ac-
3 quisition Regulations, shall enter into contracts
4 for a period of not less than **[2 years]**.

5 “(B) WAIVER.—The Secretary may waive
6 the requirements of subparagraph (A) to pro-
7 cure additional amounts of a product as nec-
8 essary—

9 “(i) to respond to a public health
10 emergency declared by the Secretary pur-
11 suant to section 319;

12 “(ii) in the interest of national secu-
13 rity; or

14 “(iii) to address an urgent need re-
15 sulting from failure to perform by an enti-
16 ty under an existing contract.”.

17 “(C) CLARIFICATION.—Subparagraph (A)
18 shall not apply to a contract for procurements
19 pursuant to subsection (c).

20 “(D) REPORTING.—An entity in receipt of
21 a contract pursuant to subparagraph (A) shall
22 submit to the Secretary such reports as the
23 Secretary may require related to the supply
24 chains for each product covered by such con-
25 tract, which may include information related to

1 potential vulnerabilities and redundancies asso-
2 ciated with such supply chains.”.

3 (b) MODIFICATION TO MINIMUM CONTRACT TERM
4 REQUIREMENTS.—Notwithstanding section 70953(b)(1)
5 of the Infrastructure Investment and Jobs Act (Public
6 Law 117–58), the requirement under such section that a
7 contract for the procurement of personal protection equip-
8 ment to be for a period of at least 2 years shall not apply
9 with respect to such a contract entered into by the Sec-
10 retary of Health and Human Services.

11 **SEC. 407. REIMBURSEMENT FOR CERTAIN SUPPLIES.**

12 Paragraph (8) of section 319F–2(a) of the Public
13 Health Service Act (42 U.S.C. 247d–6b(a)), as so redesign-
14 nated by section **【405(a)(1)(B)】**, is amended to read as
15 follows:

16 “(8) REIMBURSEMENT FOR CERTAIN SUP-
17 PLIES.—

18 “(A) IN GENERAL.—The Secretary may, at
19 appropriate intervals, make available for pur-
20 chase excess contents procured, **【using emer-
21 gency supplemental funds appropriated by Con-
22 gress,】** for, and maintained within, the stock-
23 pile under paragraph (1) to any Federal agency
24 or State, local, or Tribal government. The Sec-

1 retary shall make such contents available for
2 purchase only if—

3 “(i) the Secretary is able replenish the
4 supply in such stockpile of such contents
5 as necessary and appropriate;

6 “(ii) such contents are in excess of
7 what is required for appropriate mainte-
8 nance of such stockpile;

9 “(iii) the Secretary determines that
10 the costs for maintaining such excess con-
11 tents are not appropriate to expend to
12 meet the needs of the stockpile; and

13 “(iv) the Secretary determines that
14 such action does not compromise national
15 security.

16 “(B) REIMBURSEMENT AND COLLEC-
17 TION.—The Secretary may require reimburse-
18 ment for contents that are made available
19 under subparagraph (A), in an amount that re-
20 flects the cost of acquiring and maintaining
21 such contents and the costs incurred to make
22 available such contents in the time and manner
23 specified by the Secretary. Amounts collected
24 under this subsection shall be credited to the
25 appropriations account or fund that incurred

1 the costs to procure such contents, and shall re-
2 main available, without further appropriation,
3 until expended, for the purposes of the appro-
4 priation account or fund so credited.

5 “(C) RULE OF CONSTRUCTION.—This
6 paragraph shall not be construed to preclude
7 transfers of contents in the stockpile under
8 other authorities.

9 “(D) REPORT.—Not later than 2 years
10 after the date of enactment of the PREVENT
11 Pandemics Act, and annually thereafter, the
12 Secretary shall submit to the Committee on
13 Health, Education, Labor, and Pensions and
14 the Committee on Appropriations of the Senate
15 and the Committee on Energy and Commerce
16 and the Committee on Appropriations of the
17 House of Representatives a report on the use of
18 the authority provided under this paragraph, in-
19 cluding details of each action taken pursuant to
20 this paragraph, the account or fund to which
21 any collected amounts have been credited, and
22 how the Secretary has used such amounts.

23 “(E) SUNSET.—The authority under this
24 paragraph shall terminate on September 30,
25 2025.”.

1 **SEC. 408. ACTION REPORTING ON STOCKPILE DEPLETION.**

2 Section 319 of the Public Health Service Act (42
3 U.S.C. 247d), as amended by section **[223]**, is further
4 amended by adding at the end the following:

5 “(h) STOCKPILE DEPLETION REPORTING.—The Sec-
6 retary shall, not later than **[30]** days after the deploy-
7 ment of contents of the Strategic National Stockpile under
8 section 319F–2(a) to respond to a public health emer-
9 gency declared by the Secretary under this section, and
10 every **[30 days]** thereafter until the expiration or termi-
11 nation of such public health emergency, submit a report
12 to the Committee on Health, Education, Labor, and Pen-
13 sions and the Committee on Appropriations of the Senate
14 and the Committee on Energy and Commerce and the
15 Committee on Appropriations of the House of Representa-
16 tives on—

17 “(1) the deployment of the contents of the
18 stockpile in response to State, local, and Tribal re-
19 quests;

20 “(2) the amount of such products that remain
21 within the stockpile following such deployment; and

22 “(3) plans to replenish such products, as appro-
23 priate, including related timeframes and any barriers
24 or limitations to replenishment.”.

1 **SEC. 409. PROVISION OF MEDICAL COUNTERMEASURES TO**
2 **INDIAN PROGRAMS AND FACILITIES.**

3 (a) CLARIFICATION.—Section 319F–2(a)(3) of the
4 Public Health Service Act (42 U.S.C. 247d–6b(a)(3)) is
5 amended—

6 (1) in subparagraph (C), by striking “and
7 local” and inserting “local, and Tribal”; and

8 (2) in subparagraph (J), by striking “and
9 local” and inserting “local, and Tribal”.

10 (b) DISTRIBUTION OF MEDICAL COUNTERMEASURES
11 TO INDIAN TRIBES.—Title III of the Public Health Serv-
12 ice Act (42 U.S.C. 241 et seq.) is amended by inserting
13 after section 319F–4 the following:

14 **“SEC. 319F-5. PROVISION OF MEDICAL COUNTERMEASURES**
15 **TO INDIAN PROGRAMS AND FACILITIES.**

16 “In the event that the Secretary deploys the contents
17 of the Strategic National Stockpile under section 319F–
18 2(a), or otherwise distributes medical countermeasures to
19 States to respond to a public health emergency declared
20 by the Secretary under section 319, the Secretary shall,
21 in coordination with the applicable States, make such con-
22 tents or countermeasures directly available to Indian
23 Tribes and Tribal organizations (as such terms are de-
24 fined in section 4 of the Indian Self-Determination and
25 Education Assistance Act (25 U.S.C. 5304)【, which may
26 include through health programs or facilities operated by

1 the Indian Health Service], that are affected by such pub-
2 lic health emergency.”.

3 **SEC. 410. GRANTS FOR STATE STRATEGIC STOCKPILES.**

4 (a) Section 319F–2 of the Public Health Service Act
5 (42 U.S.C. 247d–6b) is amended by adding at the end
6 the following:

7 “(i) PILOT PROGRAM TO SUPPORT STATE MEDICAL
8 STOCKPILES.—

9 “(1) IN GENERAL.—The Secretary, in consulta-
10 tion with the Assistant Secretary for Preparedness
11 and Response and the Director of the Centers for
12 Disease Control and Prevention, shall award grants
13 or cooperative agreements to not fewer than 5
14 States, or consortia of States, to establish, expand,
15 or maintain a stockpile of appropriate drugs, vac-
16 cines and other biological products, medical devices,
17 and other medical supplies determined by the State
18 to be necessary to respond to a public health emer-
19 gency declared by the Governor of a State or by the
20 Secretary under section 319, or a major disaster or
21 emergency declared by the President under section
22 401 or 501, respectively, of the Robert T. Stafford
23 Disaster Relief and Emergency Assistance Act, in
24 order to support the preparedness goals described in

1 paragraphs (2) through (6) and (8) of section
2 2802(b).

3 “(2) REQUIREMENTS.—

4 “(A) APPLICATION.—To be eligible to re-
5 ceive an award under paragraph (1), an entity
6 shall prepare, in consultation with appropriate
7 health care entities and health officials within
8 the jurisdiction of such State or States, and
9 submit to the Secretary an application that con-
10 tains such information as the Secretary may re-
11 quire, including—

12 “(i) a plan for such stockpile, con-
13 sistent with paragraph (4), including a de-
14 scription of the activities such entity will
15 carry out under the agreement and an out-
16 line of proposed expenses; and

17 “(ii) a description of how such entity
18 will coordinate with relevant entities in re-
19 ceipt of an award under section 319C-1
20 pursuant to paragraph (4), including
21 through promoting alignment between the
22 stockpile plan established pursuant to
23 clause (i) and applicable plans that are es-
24 tablished by such entity pursuant to sec-
25 tion 319C-1.

1 “(B) MATCHING FUNDS.—

2 “(i) Subject to clause (ii), the Sec-
3 retary may not make an award under this
4 subsection unless the applicant agrees,
5 with respect to the costs to be incurred by
6 the applicant in carrying out the purpose
7 described in this subsection, to make avail-
8 able non-Federal contributions toward such
9 costs in an amount equal to—

10 “(I) for each of fiscal years 2023
11 and 2024, not less than \$1 for each
12 **[\$10]** of Federal funds provided in
13 the award;

14 “(II) for each of fiscal years
15 2025 and 2026, not less than \$1 for
16 each **[\$5]** of Federal funds provided
17 in the award; and

18 “(III) for fiscal year 2027 and
19 each fiscal year thereafter, not less
20 than \$1 for each **[\$3]** of Federal
21 funds provided in the award.

22 “(ii) WAIVER.—The Secretary may,
23 upon the request of a State, waive the re-
24 quirement under clause (i), in whole or in
25 part, if the Secretary determines that ex-

1 traordinary economic conditions in the
2 State in the fiscal year involved or in the
3 previous fiscal year justify the waiver. A
4 waiver provided by the Secretary under
5 this subparagraph shall apply only to the
6 fiscal year involved.

7 “(C) ADMINISTRATIVE EXPENSES.—Not
8 more than 10 percent of amounts received by
9 an entity pursuant to an award under this sub-
10 section may be used for administrative ex-
11 penses.

12 “(3) LEAD ENTITY.—An entity in receipt of an
13 award under paragraph (1) may designate a lead en-
14 tity, which may be a public or private entity, as ap-
15 propriate, to manage the stockpile at the direction of
16 the State or consortium of States.

17 “(4) USE OF FUNDS.—An entity in receipt of
18 an award under paragraph (1) shall use such funds
19 to—

20 “(A) purchase, store, and maintain a
21 stockpile of appropriate drugs, vaccines and
22 other biological products, medical devices, and
23 other medical supplies to be used during a pub-
24 lic health emergency, major disaster, or emer-
25 gency described in paragraph (1), in such num-

1 bers, types, and amounts as the entity deter-
2 mines necessary, consistent with such entity's
3 stockpile plan established pursuant to para-
4 graph (2)(A)(i);

5 “(B) deploy the stockpile as required by
6 the entity to respond to an actual or potential
7 public health emergency, major disaster, or
8 other emergency described in paragraph (1);

9 “(C) replenish and make necessary addi-
10 tions or modifications to the contents of such
11 stockpile, including to address potential deple-
12 tion;

13 “(D) in consultation with Federal, State,
14 and local officials, take into consideration the
15 availability, deployment, dispensing, and admin-
16 istration requirements of medical products with-
17 in the stockpile;

18 “(E) ensure that procedures are followed
19 for inventory management and accounting, and
20 for the physical security of the stockpile, as ap-
21 propriate;

22 “(F) review and revise, as appropriate, the
23 contents of the stockpile on a regular basis to
24 ensure that, to the extent practicable, new tech-
25 nologies and medical products are considered;

1 “(G) carry out exercises, drills, and other
2 training for purposes of stockpile deployment,
3 dispensing, and administration of medical prod-
4 ucts, and for purposes of assessing the capa-
5 bility of such stockpile to address the medical
6 supply needs of public health emergencies,
7 major disasters, or other emergencies described
8 in paragraph (1) of varying types and scales,
9 which may be conducted in accordance with re-
10 quirements related to exercises, drills, and other
11 training for recipients of awards under section
12 319C–1 or 319C–2, as applicable; and

13 “(H) carry out other activities as the enti-
14 ty determines appropriate, to support State ef-
15 forts to prepare for, and respond to, public
16 health threats.

17 “(5) SUPPLEMENT NOT SUPPLANT.—Awards
18 under paragraph (1) shall supplement, not supplant,
19 the maintenance and use of the Strategic National
20 Stockpile by the Secretary under subsection (a).

21 “(6) GUIDANCE FOR STATES.—Not later than
22 180 days after the date of enactment of this sub-
23 section, the Secretary, in consultation with States,
24 health officials, and other relevant stakeholders, as
25 appropriate, shall issue guidance, and update such

1 guidance as appropriate, for States related to main-
2 taining and replenishing a stockpile of medical prod-
3 ucts, which may include strategies and best practices
4 related to—

5 “(A) types of medical products and med-
6 ical supplies that are critical to respond to pub-
7 lic health emergencies, and may be appropriate
8 for inclusion in a stockpile by States, with con-
9 sideration of threats that require the large-scale
10 and simultaneous deployment of stockpiles, in-
11 cluding the stockpile maintained by the Sec-
12 retary pursuant to subsection (a), and long-
13 term public health and medical response needs;

14 “(B) appropriate management of the con-
15 tents of a stockpile, including management by
16 vendors of reserve amounts of medical products
17 and supplies intended to be delivered to the
18 ownership of the State and appropriate disposi-
19 tion of excess products, as applicable; and

20 “(C) the procurement of medical products
21 and medical supplies consistent with the Buy
22 American Act of 1933.

23 “(7) TECHNICAL ASSISTANCE.—The Secretary
24 shall provide assistance to States, including technical
25 assistance, as appropriate, in establishing, maintain-

1 ing, improving, and utilizing a medical stockpile, in-
2 cluding appropriate inventory management and dis-
3 position of products.

4 “(8) REPORTING.—

5 “(A) STATE REPORTS.—Each entity re-
6 ceiving an award under paragraph (1) shall up-
7 date, as appropriate, the plan established pur-
8 suant to paragraph (2)(A)(i) and submit to the
9 Secretary an annual report on implementation
10 of such plan, including any changes to the con-
11 tents of the stockpile supported under such
12 award. The Secretary shall use information ob-
13 tained from such reports to inform the mainte-
14 nance and management of the Strategic Na-
15 tional Stockpile pursuant to subsection (a).

16 “(B) REPORTS TO CONGRESS.—Not later
17 than **[1]** year after the initial issuance of
18 awards pursuant to paragraph (1), and annu-
19 ally thereafter for the duration of the program
20 established under this subsection, the Secretary
21 shall submit to the Committee on Health, Edu-
22 cation, Labor, and Pensions of the Senate and
23 the Committee on Energy and Commerce of the
24 House of Representatives a report on such pro-
25 gram, 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 **TITLE V—ENHANCING DEVELOP-**
14 **MENT AND COMBATING**
15 **SHORTAGES OF MEDICAL**
16 **PRODUCTS**

17 **Subtitle A—Development and**
18 **Review**

19 **SEC. 501. ADVANCING QUALIFIED INFECTIOUS DISEASE**
20 **PRODUCT INNOVATION.**

21 (a) IN GENERAL.—Section 505E of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amend-
23 ed—

24 (1) in subsection (c)—

1 (A) in paragraph (2), by striking “; or”
2 and inserting “;”;

3 (B) in paragraph (3), by striking the pe-
4 riod and inserting “; or”; and

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

6 “(4) an application pursuant to section 351(a)
7 of the Public Health Service Act.”;

8 (2) in subsection (d)(1), by inserting “of this
9 Act or section 351(a) of the Public Health Service
10 Act” after “section 505(b)”; and

11 (3) by amending subsection (g) to read as fol-
12 lows:

13 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
14 The term ‘qualified infectious disease product’ means a
15 drug for human use that—

16 “(1) is—

17 “(A) an antibacterial or antifungal drug;
18 or

19 “(B) a biological product that acts directly
20 on bacteria or fungi or on substances produced
21 by such bacteria or fungi; and

22 “(2) is intended to treat a serious or life-threat-
23 ening infection, including such an infection caused
24 by—

1 “(A) an antibacterial or antifungal resist-
2 ant pathogen, including novel or emerging in-
3 fectious pathogens; or

4 “(B) qualifying pathogens listed by the
5 Secretary under subsection (f).”.

6 (b) PRIORITY REVIEW.—Section 524A(a) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a))
8 is amended by inserting “of this Act, or section 351(a)
9 of the Public Health Service Act, that requires clinical
10 data (other than bioavailability studies) to demonstrate
11 safety or effectiveness” before the period.

12 **SEC. 502. MODERNIZING CLINICAL TRIALS.**

13 (a) CLARIFYING THE USE OF DIGITAL HEALTH
14 TECHNOLOGIES IN CLINICAL TRIALS.—

15 (1) IN GENERAL.—Not later than 1 year after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services (referred to in this sec-
18 tion as the “Secretary”) shall issue draft guidance
19 regarding the appropriate use of validated digital
20 health technologies in clinical trials to help improve
21 recruitment for, retention in, participation in, and
22 data collection during, clinical trials, and provide for
23 novel clinical trial designs utilizing such technology
24 for purposes of supporting the development of, and
25 review of applications for, drugs and devices. Not

1 later than 18 months after the public comment pe-
2 riod on such draft guidance ends, the Secretary shall
3 issue a revised draft guidance or final guidance.

4 (2) CONTENT.—The guidance described in
5 paragraph (1) shall include—

6 (A) recommendations for data collection
7 methodologies by which sponsors may incor-
8 porate the use of digital health technologies in
9 clinical trials to collect data remotely from trial
10 participants;

11 (B) considerations for privacy and security
12 protections for data collected during a clinical
13 trial, including—

14 (i) recommendations for the protec-
15 tion of trial participant data that is col-
16 lected or used in research, using digital
17 health technologies; and

18 (ii) compliance with the regulations
19 promulgated under section 264(c) of the
20 Health Insurance Portability and Account-
21 ability Act of 1996 (42 U.S.C. 1320d–2
22 note), subpart B of part 50 of title 21,
23 Code of Federal Regulations, subpart C of
24 part 56 of title 21, Code of Federal Regu-
25 lations, the Federal policy for the protec-

1 tion of human subjects under subpart A of
2 part 46 of title 45, Code of Federal Regu-
3 lations (commonly known as the “Common
4 Rule”), and part 2 of title 42, Code of
5 Federal Regulations (or any successor reg-
6 ulations);

7 (C) considerations on data collection meth-
8 ods to help increase recruitment of clinical trial
9 participants and the level of participation of
10 such participants, reduce burden on clinical
11 trial participants, and optimize data quality;

12 (D) recommendations for the use of elec-
13 tronic methods to obtain informed consent from
14 clinical trial participants, taking into consider-
15 ation applicable Federal law, including subpart
16 B of part 50 of title 21, Code of Federal Regu-
17 lations (or successor regulations), and, as ap-
18 propriate, State law;

19 (E) best practices for communication and
20 early engagement between sponsors and the
21 Secretary on the development of data collection
22 methods;

23 (F) the appropriate format to submit such
24 data to the Secretary;

1 (G) a description of the manner in which
2 the Secretary will assess or evaluate data col-
3 lected through digital health technologies to
4 support the development and approval, licen-
5 sure, clearance, or authorization of the drug or
6 device; and

7 (H) recommendations for increasing access
8 to, and the use of, digital health technologies in
9 clinical trials to facilitate the inclusion of di-
10 verse and underrepresented populations, as ap-
11 propriate.

12 (b) ADVANCING DECENTRALIZED CLINICAL
13 TRIALS.—

14 (1) IN GENERAL.—Not later than 1 year after
15 the date of enactment of this Act, the Secretary
16 shall issue draft guidance to provide recommenda-
17 tions to clarify and advance the use of decentralized
18 clinical trials to support the development of drugs
19 and devices and help improve trial participant en-
20 gagement and advance the use of flexible and novel
21 clinical trial designs. Not later than 1 year after the
22 public comment period on such draft guidance ends,
23 the Secretary shall issue a revised draft guidance or
24 final guidance.

1 (2) CONTENT.—The guidance described in
2 paragraph (1) shall include—

3 (A) recommendations for methods of re-
4 mote data collection, including trial participant
5 experience data, though the use of digital health
6 technologies, telemedicine, local laboratories,
7 local health care providers, or other options for
8 data collection;

9 (B) considerations for sponsors to mini-
10 mize or reduce burdens for clinical trial partici-
11 pants associated with participating in a clinical
12 trial, such as the use of digital technologies,
13 telemedicine, local laboratories, local health care
14 providers, or other data collection or assessment
15 options, health care provider home visits, direct-
16 to-participant shipping of investigational drugs
17 and devices, and electronic informed consent, as
18 appropriate;

19 (C) recommendations regarding conducting
20 decentralized clinical trials to facilitate and en-
21 courage diversity among the clinical trial par-
22 ticipants, as appropriate;

23 (D) recommendations for strategies and
24 methods for recruiting, retaining, and engaging
25 with clinical trial participants, including com-

1 munication regarding the role of trial partici-
2 pants and community partners to facilitate clin-
3 ical trial recruitment and engagement, including
4 with respect to diverse and underrepresented
5 populations, as appropriate;

6 (E) considerations for review and oversight
7 by sponsors and institutional review boards, in-
8 cluding remote trial oversight;

9 (F) recommendations for decentralized
10 clinical trial protocol designs and processes for
11 evaluating such proposed trial designs;

12 (G) recommendations for digital health
13 technology and other remote assessment tools
14 that may support decentralized clinical trials,
15 including guidance on appropriate technological
16 platforms and tools, data collection and use,
17 data integrity, and communication to clinical
18 trial participants through such technology;

19 (H) a description of the manner in which
20 the Secretary will assess or evaluate data col-
21 lected within a decentralized clinical trial to
22 support the development of the drug or device,
23 if the manner is different from that used for a
24 non-decentralized trial;

1 (I) considerations for sponsors to validate
2 digital technologies and establish appropriate
3 clinical endpoints for use in decentralized trials;
4 and

5 (J) considerations for privacy and security
6 of personally identifiable information of trial
7 participants.

8 (c) SEAMLESS AND CONCURRENT CLINICAL
9 TRIALS.—

10 (1) IN GENERAL.—Not later than 1 year after
11 the date of enactment of this Act, the Secretary
12 shall update or issue draft guidance on the use of
13 seamless, concurrent, and other innovative clinical
14 trial designs to support the expedited development
15 and review of applications for drugs under section
16 505 of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355) or section 351 of the Public Health
18 Service Act (42 U.S.C. 262), as appropriate. Not
19 later than 1 year after the public comment period on
20 such draft guidance ends, the Secretary shall issue
21 a revised draft guidance or final guidance.

22 (2) CONTENT.—The guidance described in
23 paragraph (1) shall include—

24 (A) recommendations on the use of expan-
25 sion cohorts and other seamless clinical trial de-

1 signs to assess different aspects of product can-
2 didates in one continuous trial, including how
3 such clinical trial designs, including how such
4 clinical trial designs can be used as part of
5 meeting the substantial evidence standard
6 under section 505(d) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355(d));

8 (B) recommendations on the use of clinical
9 trial designs that involve the concurrent con-
10 duct of different or multiple clinical trial
11 phases, and the concurrent conduct of pre-
12 clinical testing, to expedite the development of
13 new drugs;

14 (C) recommendations for how to streamline
15 trial logistics and facilitate the efficient collec-
16 tion and analysis of clinical trial data, including
17 any planned interim analyses;

18 (D) considerations to assist sponsors in en-
19 suring the rights, safety, and welfare of clinical
20 trial participants, maintaining compliance with
21 good clinical practice regulations, minimizing
22 risks to clinical trial data integrity, and ensur-
23 ing the reliability of clinical trial results;

24 (E) recommendations for communication
25 and early engagement between sponsors and the

1 Food and Drug Administration on the develop-
2 ment of seamless, concurrent, or other adaptive
3 trial designs, including review of, and feedback
4 on, clinical trial protocols; and

5 (F) a description of the manner in which
6 the Secretary will assess or evaluate data col-
7 lected through seamless, concurrent, or other
8 adaptive trial designs to support the develop-
9 ment of the drug.

10 (d) INTERNATIONAL HARMONIZATION.—The Sec-
11 retary may work with foreign regulators pursuant to
12 memoranda of understanding or other arrangements gov-
13 erning the exchange of information to facilitate inter-
14 national harmonization of the regulation and use of decen-
15 tralized clinical trials, digital technology in clinical trials,
16 and seamless, concurrent, and other adaptive or innovative
17 clinical trial designs.

18 **SEC. 503. ACCELERATING COUNTERMEASURE DEVELOP-**
19 **MENT AND REVIEW.**

20 Section 565 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 360bbb–4) is amended by adding at the
22 end the following:

23 “(h) ACCELERATING COUNTERMEASURE DEVELOP-
24 MENT AND REVIEW DURING AN EMERGENCY.—

1 “(1) ACCELERATION OF COUNTERMEASURE DE-
2 VELOPMENT AND REVIEW.—The Secretary may, at
3 the request of the sponsor of a countermeasure, dur-
4 ing a domestic, military, or public health emergency
5 or material threat described in section
6 564A(a)(1)(C) expedite the development and review
7 of countermeasures for approval, licensure, clear-
8 ance, or authorization under this title or section 351
9 of the Public Health Service Act.

10 “(2) ACTIONS.—The actions to expedite the de-
11 velopment and review of a countermeasure under
12 paragraph (1) may include the following:

13 “(A) Expedited review of submissions
14 made by sponsors of countermeasures to the
15 Food and Drug Administration, including roll-
16 ing submissions of countermeasure applications
17 and other submissions.

18 “(B) Expedited and increased engagement
19 with sponsors regarding countermeasure devel-
20 opment and manufacturing, including—

21 “(i) holding meetings with the sponsor
22 and the review team and providing timely
23 advice to, and interactive communication
24 with, the sponsor regarding the develop-
25 ment of the countermeasure to ensure that

1 the development program to gather the
2 nonclinical and clinical data necessary for
3 approval, licensure, clearance, or author-
4 ization is as efficient as practicable;

5 “(ii) involving senior managers and
6 experienced review staff, as appropriate, in
7 a collaborative, cross-disciplinary review;

8 “(iii) assigning a cross-disciplinary
9 project lead for the review team to facili-
10 tate; and

11 “(iv) taking steps to ensure that the
12 design of the clinical trials is as efficient as
13 practicable, when scientifically appropriate,
14 such as by minimizing the number of pa-
15 tients exposed to a potentially less effica-
16 cious treatment.

17 “(C) Expedited issuance of guidance docu-
18 ments and publication of other regulatory infor-
19 mation regarding countermeasure development
20 and manufacturing.

21 “(D) Other steps to expedite the develop-
22 ment and review of a countermeasure applica-
23 tion submitted for approval, licensure, clear-
24 ance, or authorization, as the Secretary deter-
25 mines appropriate.

1 “(3) LIMITATION OF EFFECT.—Nothing in this
2 subsection shall be construed to require the Sec-
3 retary to grant, or take any other action related to,
4 a request of a sponsor to expedite the development
5 and review of a countermeasure for approval, licen-
6 sure, clearance, or authorization under paragraph
7 (1).”.

8 **SEC. 504. THIRD PARTY TEST EVALUATION DURING EMER-**
9 **GENCIES.**

10 (a) IN GENERAL.—Section 565 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 360bbb-4), as amend-
12 ed by section 503, is further amended by adding at the
13 end the following:

14 “(i) THIRD PARTY EVALUATION OF TESTS USED
15 DURING AN EMERGENCY.—

16 “(1) IN GENERAL.—For purposes of conducting
17 evaluations and making recommendations regarding
18 the validity, accuracy, and reliability of in vitro diag-
19 nostic products (as defined in section 809.3 of title
20 21, Code of Federal Regulations (or its successor
21 regulations)) submitted for emergency use authoriza-
22 tion under section 564, the Secretary may, as appro-
23 priate, consult with persons with respect to such
24 evaluations and recommendations or enter into coop-
25 erative agreements or contracts with persons under

1 which such persons conduct such evaluations and
2 make such recommendations.

3 “(2) REQUIREMENTS REGARDING EVALUATIONS
4 AND RECOMMENDATIONS.—

5 “(A) IN GENERAL.—In evaluating and
6 making recommendations to the Secretary re-
7 garding the validity, accuracy, and reliability of
8 in vitro diagnostic products, as described in
9 paragraph (1), a person shall consider and doc-
10 ument whether the relevant criteria under sub-
11 section (c)(2) of section 564 for issuance of au-
12 thorization under such section are met with re-
13 spect to the in vitro diagnostic product.

14 “(B) WRITTEN RECOMMENDATIONS.—Rec-
15 ommendations made by a person under this
16 subsection shall be submitted to the Secretary
17 in writing, and shall include the reasons for
18 such recommendation and other information
19 that may be requested by the Secretary.”.

20 (b) GUIDANCE.—Not later than 1 year after the date
21 of enactment of this Act, the Secretary of Health and
22 Human Services (referred to in this subsection as the
23 “Secretary”) shall issue draft guidance on consultations
24 with persons under subsection (i) of section 565 of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360bbb-4), as added by subsection (a), including consider-
2 ations concerning conflicts of interest, compensation ar-
3 rangements, and information sharing. Not later than 1
4 year after the public comment period on such draft guid-
5 ance ends, the Secretary shall issue a revised draft guid-
6 ance or final guidance.

7 **SEC. 505. FACILITATING THE USE OF REAL WORLD EVI-**
8 **DENCE.**

9 Not later than 1 year after the date of enactment
10 of this Act, the Secretary of Health and Human Services
11 shall issue or revise existing guidance on considerations
12 for the use of real world data and real world evidence to
13 support regulatory decision-making, as follows:

14 (1) With respect to drugs, such guidance shall
15 address the use of such data and evidence to support
16 the approval of a drug application under section 505
17 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) or a biological product application
19 under section 351 of the Public Health Service Act
20 (42 U.S.C. 262), or to support an investigational use
21 exemption under section 505(i) of the Federal Food,
22 Drug, and Cosmetic Act or section 351(a)(3) of the
23 Public Health Service Act. Such guidance shall in-
24 clude considerations for the inclusion, in such appli-
25 cations, of real world data and real world evidence

1 obtained as a result of the use of drugs authorized
2 for emergency use under section 564 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–
4 3).

5 (2) With respect to devices, such guidance shall
6 address the use of such data and evidence to support
7 the approval, clearance, or classification of a device
8 pursuant to an application or submission submitted
9 under section 510(k), 513(f)(2), or 515 of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.
11 360(k), 360c(f)(2), 360e), or to support an inves-
12 tigational use exemption under section 520(g) of
13 such Act (21 U.S.C. 360j(g)). Such guidance shall
14 include considerations for the inclusion, in such ap-
15 plications, submissions, or requests, of real world
16 data and real world evidence obtained as a result of
17 the use of devices authorized for emergency use
18 under section 564 of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 360bbb–3).

20 **SEC. 506. ADVANCED PLATFORM TECHNOLOGIES.**

21 Chapter V of the Federal Food, Drug, and Cosmetic
22 Act is amended by inserting after section 506J of such
23 Act (21 U.S.C. 356j) the following:

1 **“SEC. 506K. ADVANCED PLATFORM TECHNOLOGY.**

2 “(a) IN GENERAL.—The Secretary shall establish a
3 process for the designation of advanced platform tech-
4 nologies that meet the criteria described in subsection (b).

5 “(b) CRITERIA.—A platform technology incorporated
6 within or utilized by a drug is eligible for designation as
7 an advanced platform technology under this section if—

8 “(1) the platform technology is incorporated in,
9 or utilized by, a drug approved under section 505 of
10 this Act or a biological product licensed under sec-
11 tion 351 of the Public Health Service Act;

12 “(2) preliminary evidence submitted by the
13 sponsor of the approved or licensed drug described
14 in paragraph (1)【, or a sponsor that has been grant-
15 ed a right of reference to data submitted in the ap-
16 plication for such drug】, in a submission for an in-
17 vestigational use exemption under section 505(i) of
18 this Act or section 351(a)(3) of the Public Health
19 Service Act or in an application under section
20 505(b) of this Act or under section 351(a) of the
21 Public Health Service Act for a subsequent drug,
22 demonstrates that the platform technology has the
23 potential to be incorporated in, or utilized by, more
24 than one drug without an adverse effect on quality,
25 manufacturing, or safety; and

1 “(3) data or information submitted by the ap-
2 plicable sponsor under paragraph (2) indicates that
3 incorporation or utilization of the platform tech-
4 nology has a reasonable likelihood to bring signifi-
5 cant efficiencies to the drug development and review
6 processes.

7 “(c) REQUEST FOR DESIGNATION.—The sponsor of
8 a drug may request the Secretary designate a platform
9 technology as an advanced platform technology concur-
10 rently with, or at any time after, submission under section
11 505(i) of this Act or section 351(a)(3) of the Public
12 Health Service Act for the investigation of a drug that
13 incorporates or utilizes the platform technology that is the
14 subject of the request.

15 “(d) DESIGNATION.—

16 “(1) IN GENERAL.—Not later than 60 calendar
17 days after the receipt of a request under subsection
18 (c), the Secretary shall determine whether the plat-
19 form technology that is the subject of the request
20 meets the criteria described in subsection (b).

21 “(2) DESIGNATION.—If the Secretary deter-
22 mines that the platform technology meets the cri-
23 teria described in subsection (b), the Secretary shall
24 designate the platform technology as an advanced
25 platform technology [and shall expedite the develop-

1 ment and review of any subsequent application sub-
2 mitted under section 505(b) of this Act or section
3 351(a) of the Public Health Service Act for a drug
4 that uses or incorporates the platform technology
5 pursuant to subsection (e), as appropriate**】**.

6 “(3) DETERMINATION NOT TO DESIGNATE.—If
7 the Secretary determines that the platform tech-
8 nology does not meet the criteria under subsection
9 (b), the Secretary shall include with the determina-
10 tion not to designate the technology a written de-
11 scription of the rationale for such determination.

12 “(4) REVOCATION OF DESIGNATION.—The Sec-
13 retary may revoke a designation made under para-
14 graph (2), if the Secretary determines that the des-
15 ignated platform technology no longer meets the cri-
16 teria described in subsection (b). The Secretary shall
17 communicate the determination to revoke a designa-
18 tion to the requesting sponsor in writing, including
19 a description of the rationale for such determination.

20 “(e) ACTIONS.—The Secretary may take actions to
21 expedite the development and review of an application for
22 a drug that incorporates or utilizes an advanced platform
23 technology, including—

24 “(1) engaging in early interactions with the
25 sponsor to discuss the use of the advanced platform

1 technology and what is known about such tech-
2 nology, including data previously submitted that is
3 relevant to establishing, as applicable, safety or effi-
4 cacy under section 505(b) of this Act or safety, pu-
5 rity, or potency under section 351(a) of the Public
6 Health Service Act;

7 “(2) providing timely advice to, and interactive
8 communication with, the sponsor regarding the de-
9 velopment of the drug that proposes to use the ad-
10 vanced platform technology to ensure that the devel-
11 opment program designed to gather data necessary
12 for approval or licensure is as efficient as prac-
13 ticable, which may include holding meetings with the
14 sponsor and the review team throughout the develop-
15 ment of the drug; and

16 “(3) considering inspectional findings related to
17 the manufacture of a drug that incorporates or uti-
18 lizes the advanced platform technology.

19 “(f) LEVERAGING DATA FROM ADVANCED PLAT-
20 FORM TECHNOLOGIES.—The Secretary shall, consistent
21 with applicable standards for approval, authorization, or
22 licensure under this Act and section 351(a) of the Public
23 Health Service Act, allow the sponsor of an application
24 under section 505(b) of this Act or section 351(a) of the
25 Public Health Service Act or a request for emergency use

1 authorization under section 564, in order to support ap-
2 proval, licensure, or authorization, to reference or rely
3 upon data and information within such application or re-
4 quest that incorporates or utilizes the same **【**or substan-
5 tially similar**】** advanced platform technology designated
6 under subsection (d), provided that—

7 “(1) such data and information was developed
8 by the same sponsor, pursuant to the application for
9 the drug with respect to which designation of the ad-
10 vanced platform technology under subsection (d) was
11 granted; or

12 “(2) the sponsor relying on such data and in-
13 formation received a right of reference to such data
14 and information from the sponsor described in para-
15 graph (1).

16 **【**“(g) CHANGES TO AN ADVANCED PLATFORM TECH-
17 NOLOGY.—A major change to an advanced platform tech-
18 nology may be made, and the drug as made with the
19 change to the advanced platform technology may be dis-
20 tributed, if the holder of an approved application of a drug
21 or licensure of a biological product incorporating or uti-
22 lizing such advanced platform technology receives approval
23 or licensure of a supplemental application for such
24 changes with respect to the platform technology. For
25 changes that are not major changes, the Secretary **【**may

1 authorize】 holders of approved applications or licenses, as
2 applicable, to distribute such drugs without submitting a
3 supplemental application for such changes.】

4 “(h) GUIDANCE.—Not later than 1 year after the
5 date of enactment of this section, the Secretary shall issue
6 draft guidance on the implementation of this section. Such
7 guidance shall include examples of drugs that can be man-
8 ufactured using platform technologies, including drugs
9 that contain or consist of vectors and nucleic acids, infor-
10 mation about the Secretary’s review of platform tech-
11 nologies, the implementation of the advanced platform
12 technology designation program, efficiencies that may be
13 achieved in the development and review of products that
14 incorporate or utilize advanced platform technologies, and
15 recommendations and requirements for making and re-
16 porting manufacturing changes to an advanced platform
17 technology in accordance with section 506A.

18 “(i) DEFINITIONS.—For purposes of this section:

19 “(1) The term ‘platform technology’ means—

20 “(A) a technology incorporated into a
21 drug, such as a vector, nucleic acid, compounds
22 with a common or similar chemistry, mecha-
23 nism of action, delivery method or vehicle 【(ex-
24 cluding packaging components)】, other tech-
25 nology the Secretary determines to be appro-

1 priate, or combination of any such technologies,
2 that—

3 “(i) is essential to the characterization
4 of the drug; and

5 “(ii) can be adapted for, or incor-
6 porated or utilized in, more than one drug;

7 or

8 “(B) a standardized production or manu-
9 facturing process that is used to create or de-
10 velop more than one drug sharing common
11 structural elements that can be incorporated
12 into multiple different drugs.

13 “(2) The term ‘advanced platform technology’
14 means a platform technology that is designated as
15 an advanced platform technology under subsection
16 (d).

17 “(j) RULE OF CONSTRUCTION.—Nothing in this sec-
18 tion shall be construed to—

19 “(1) alter the authority of the Secretary to ap-
20 prove drugs pursuant to section 505 of this Act or
21 license biological products pursuant to section 351 of
22 the Public Health Service Act, including standards
23 of evidence and applicable conditions for approval or
24 licensure under the applicable Act; or

1 “(2) confer any new rights with respect to the
2 permissibility of a sponsor of an application for a
3 drug product or biological product referencing infor-
4 mation contained in another application submitted
5 by the holder of an approved application under sec-
6 tion 505(c) of this Act or of a license under section
7 351(a) of the Public Health Service Act.”.

8 **SEC. 507. INCREASING EUA DECISION TRANSPARENCY.**

9 Section 564(h)(1) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 360bbb-3(h)(1)) is amended—

11 (1) by inserting “on the internet website of the
12 Food and Drug Administration and” after “prompt-
13 ly publish”; and

14 (2) by striking “application under section
15 505(i), 512(j), or 520(g), even if such summary may
16 indirectly reveal the existence of such application”
17 and inserting “application, request, or submission
18 under this section or section 505(b), 505(i), 505(j),
19 512(b), 512(j), 512(n), 515, 510(k), 513(f)(2),
20 520(g), 520(m), 571, or 572 of this Act, or section
21 351(a) or 351(k) of the Public Health Service Act,
22 even if such summary may reveal the existence of
23 such an application, request, or submission, or data
24 contained in such application, request, or submis-
25 sion”.

1 **SEC. 508. IMPROVING FDA GUIDANCE AND COMMUNICA-**
2 **TION.**

3 (a) FDA REPORT AND IMPLEMENTATION OF GOOD
4 GUIDANCE PRACTICES.—The Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”) shall develop, and publish on the website of the
7 Food and Drug Administration—

8 (1) a report identifying best practices for the
9 efficient prioritization, development, issuance, and
10 use of guidance documents, within centers, across
11 the Food and Drug Administration, and across other
12 applicable agencies; and

13 (2) a plan for implementation of such best
14 practices, including across other applicable agencies,
15 which shall address—

16 (A) streamlining development and review
17 of guidance documents within centers and
18 across the Food and Drug Administration;

19 (B) streamlining processes for regulatory
20 submissions to the Food and Drug Administra-
21 tion, including through the revision or issuance
22 of guidance documents; and

23 (C) implementing innovative guidance de-
24 velopment processes and practices and
25 transitioning or updating guidance issued dur-

1 ing the COVID–19 public health emergency, as
2 appropriate.

3 (b) REPORT AND IMPLEMENTATION OF FDA BEST
4 PRACTICES FOR COMMUNICATING WITH EXTERNAL
5 STAKEHOLDERS.—The Secretary, acting through the
6 Commissioner of Food and Drugs, shall develop and pub-
7 lish on the website of the Food and Drug Administration
8 a report on the practices of the Food and Drug Adminis-
9 tration to broadly communicate with external stake-
10 holders, other than through guidance documents, which
11 shall include—

12 (1) a review of the types and methods of public
13 communication that the Food and Drug Administra-
14 tion uses to communicate and interact with medical
15 product sponsors and other external stakeholders;

16 (2) the identification of best practices for the
17 efficient development, issuance, and use of such
18 communications; and

19 (3) a plan for implementation of best practices
20 for communication with external stakeholders, which
21 shall address—

22 (A) advancing the use of innovative forms
23 of communication, including novel document
24 types and formats, to provide increased regu-
25 latory clarity to product sponsors and other

1 stakeholders, and advancing methods of com-
2 municating and interacting with medical prod-
3 uct sponsors and other external stakeholders,
4 including the use of tools such as product sub-
5 mission templates, webinars, and frequently
6 asked questions communications;

7 (B) streamlining processes for regulatory
8 submissions; and

9 (C) implementing innovative communica-
10 tion development processes and transitioning or
11 updating communication practices used during
12 the COVID–19 public health emergency, as ap-
13 propriate.

14 (e) CONSULTATION.—In developing and publishing
15 the report and implementation plan under this section, the
16 Secretary shall consult with stakeholders, including re-
17 searchers, academic organizations, pharmaceutical, bio-
18 technology, and medical device developers, clinical re-
19 search organizations, clinical laboratories, patient groups,
20 and other appropriate stakeholders.

21 (d) MANNER OF ISSUANCE.— For purposes of car-
22 rying out this section, the Secretary may update an exist-
23 ing report or plan, and may combine the reports and im-
24 plementation plans described in subsections (a) and (b)
25 into one or more documents.

1 (e) TIMING.—The Secretary shall—

2 (1) not later than 1 year after the date of en-
3 actment of this Act, publish a draft of the reports
4 and plans required under this section; and

5 (2) not later than 180 days after publication of
6 the draft reports and plans under paragraph (1)—

7 (A) publish a final report and plan; and

8 (B) begin implementation of the best prac-
9 tices pursuant to such final plan.

10 **SEC. 509. GAO STUDY AND REPORT ON HIRING CHAL-**
11 **LENGES AT FDA.**

12 (a) IN GENERAL.—Not later than 18 months after
13 the date of enactment of this Act, the Comptroller General
14 of the United States shall submit to the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Committee on Energy and Commerce of the House
17 of Representatives a report assessing the policies, prac-
18 tices, processes, and programs of the Food and Drug Ad-
19 ministration with respect to hiring, recruiting, and reten-
20 tion, and the impact of such policies, practices, processes,
21 and programs on the agency’s ability to carry out its pub-
22 lic health mission, including the agency’s ability to respond
23 to the COVID–19 public health emergency. Such report
24 may involve policies, practices, processes, and programs

1 of the Department of Health and Human Services and
2 other agencies, as applicable.

3 (b) CONTENT OF REPORT.—The report required
4 under subsection (a) shall include an assessment of—

5 (1) challenges related to the efficient hiring, re-
6 cruiting, and retention of the Food and Drug Ad-
7 ministration workforce, including, as applicable, the
8 end-to-end hiring process, time to hire, multiple hir-
9 ing authorities, availability of candidates with nec-
10 essary expertise, salary levels, and vacancy rates;

11 (2) causes of the challenges identified under
12 paragraph (1), including an analysis of relevant poli-
13 cies, practices, processes, programs, organizational
14 structure, resources, training, remote work capabili-
15 ties, and data systems;

16 (3) challenges facing the Food and Drug Ad-
17 ministration workforce, including with respect to
18 workload, diversity, and morale;

19 (4) the impact of challenges identified under
20 paragraphs (1) and (3) on operations of the Food
21 and Drug Administration, including on meeting user
22 fee agreement performance goals and inspection ac-
23 tivities;

24 (5) any hiring or retention plans of the Food
25 and Drug Administration, and progress towards im-

1 plementation and the metrics to measure success of
2 such plans;

3 (6) successful or efficient hiring policies or au-
4 thorities, including any relevant hiring authorities
5 that resulted in efficient hiring for vacant positions,
6 such as temporary direct hiring authorities during
7 the COVID–19 public health emergency response;

8 (7) whether policies, practices, processes, and
9 programs related to hiring, recruiting, and retention
10 are implemented consistently across the Food and
11 Drug Administration; and

12 (8) recommendations to address challenges
13 identified, including recommendations regarding im-
14 provements to policies, practices, processes, and pro-
15 grams of the Food and Drug Administration with
16 respect to hiring, recruiting, and retention.

17 **Subtitle B—Mitigating Shortages**

18 **SEC. 511. ENSURING REGISTRATION OF FOREIGN DRUG**

19 **AND DEVICE MANUFACTURERS.**

20 (a) REGISTRATION OF CERTAIN FOREIGN ESTAB-
21 LISHMENTS.—Section 510(i) of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 360(i)) is amended by add-
23 ing at the end the following:

24 “(5) The requirements of paragraphs (1) and (2)
25 shall apply regardless of whether the drug or device under-

1 goes further manufacture, preparation, propagation,
2 compounding, or processing at a separate establishment
3 outside the United States prior to being imported or of-
4 fered for import into the United States.”.

5 (b) UPDATING REGULATIONS.—Not later than 2
6 years after the date of enactment of this Act, the Sec-
7 retary of Health and Human Services shall update regula-
8 tions, as appropriate, to implement the amendment made
9 by subsection (a).

10 **SEC. 512. EXTENDING EXPIRATION DATES FOR CERTAIN**
11 **DRUGS.**

12 (a) IN GENERAL.—Not later than 1 year after the
13 date of enactment of this Act, the Secretary of Health and
14 Human Services (referred to in this section as the “Sec-
15 retary”) shall issue draft guidance, or revise existing guid-
16 ance, to address recommendations for sponsors of applica-
17 tions under section 505 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 355) or section 351 of the Public
19 Health Service Act (42 U.S.C. 262) regarding—

20 (1) the submission of stability testing data in
21 such applications; and

22 (2) establishing in the labeling of drugs the
23 longest feasible expiration date supported by such
24 data, taking into consideration how extended expira-

1 tion dates may help prevent or mitigate drug short-
2 ages.

3 (b) REPORT.—Not later than 2 years after the date
4 of enactment of this Act, and again 2 years thereafter,
5 the Secretary shall submit to the Committee on Health,
6 Education, Labor, and Pensions of the Senate and the
7 Committee on Energy and Commerce of the House of
8 Representatives a report that includes—

9 (1) the number of drugs for which the Sec-
10 retary has requested the manufacturer make a label-
11 ing change regarding the expiration date; and

12 (2) for each drug for which the Secretary has
13 requested a labeling change with respect to the expi-
14 ration date, information regarding the circumstances
15 of such request, including—

16 (A) the name and dose of such drug;

17 (B) the rationale for the request;

18 (C) whether the drug, at the time of the
19 request, was listed on the drug shortage list
20 under section 506E of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 356e), or was at
22 risk of shortage;

23 (D) whether the request was made during
24 a public health emergency declared under sec-

1 tion 319 of the Public Health Service Act (42
2 U.S.C. 247d); and

3 (E) whether the manufacturer made the
4 requested change by the requested date, and for
5 instances where the manufacturer does not
6 make the requested change, the manufacturer's
7 justification for not making the change, if the
8 manufacturer agrees to provide such justifica-
9 tion for inclusion in the report.

10 **SEC. 513. UNANNOUNCED FOREIGN FACILITY INSPECTIONS**

11 **PILOT PROGRAM.**

12 (a) IN GENERAL.—The Secretary of Health and
13 Human Services (referred to in this section as the “Sec-
14 retary”) shall conduct a pilot program under which the
15 Secretary increases the conduct of unannounced inspec-
16 tions of foreign human drug establishments and evaluates
17 the differences between inspections of domestic and for-
18 eign human drug establishments, including the impact of
19 announcing inspections to persons who own or operate for-
20 eign human drug establishments in advance of an inspec-
21 tion. Such pilot program shall evaluate—

22 (1) differences in the number and type of viola-
23 tions of section 501(a)(2)(B) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))
25 identified during unannounced and announced in-

1 inspections of foreign human drug establishments and
2 any other significant differences between each type
3 of inspection;

4 (2) costs and benefits associated with con-
5 ducting announced and unannounced inspections of
6 foreign human drug establishments;

7 (3) barriers to conducting unannounced inspec-
8 tions of foreign human drug establishments and any
9 challenges to achieving parity between domestic and
10 foreign human drug establishment inspections; and

11 (4) approaches for mitigating any negative ef-
12 fects of conducting announced inspections of foreign
13 human drug establishments.

14 (b) PILOT PROGRAM INITIATION.—The Secretary
15 shall initiate the pilot program under this section not later
16 than 180 days after the date of enactment of this Act.

17 (c) REPORT.—The Secretary shall, not later than 180
18 days following the completion of the pilot program, make
19 available on the website of the Food and Drug Administra-
20 tion a final report on the pilot program under this section,
21 including—

22 (1) findings and any associated recommenda-
23 tions with respect to the evaluation under subsection
24 (a), including any recommendations to address iden-

1 tified barriers to conducting unannounced inspec-
2 tions of foreign human drug establishments;

3 (2) findings and any associated recommenda-
4 tions regarding how the Secretary may achieve par-
5 ity between domestic and foreign human drug in-
6 spections; and

7 (3) the number of unannounced inspections
8 during the pilot that would not be unannounced
9 under existing practices.

10 **SEC. 514. COMBATING COUNTERFEIT DEVICES.**

11 (a) PROHIBITED ACTS.—Section 301 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
13 ed by adding at the end the following:

14 “(fff)(1) Forging, counterfeiting, simulating, or false-
15 ly representing, or without proper authority using any
16 mark, stamp, tag, label, or other identification upon any
17 device or container, packaging, or labeling thereof so as
18 to render such device a counterfeit device.

19 “(2) Making, selling, disposing of, or keeping in pos-
20 session, control, or custody, or concealing any punch, die,
21 plate, stone, or other thing designed to print, imprint, or
22 reproduce the trademark, trade name, or other identifying
23 mark or imprint of another or any likeness of any of the
24 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)”; and

3 (2) by inserting “, (F) Any device that is a
4 counterfeit device, (G) Any container, packaging, or
5 labeling of a counterfeit device, and (H) Any punch,
6 die, plate, stone, labeling, container, or other thing
7 used or designed for use in making a counterfeit de-
8 vice or devices” before the period.

9 **SEC. 515. STRENGTHENING MEDICAL DEVICE SUPPLY**
10 **CHAINS.**

11 (a) IN GENERAL.—Section 506J of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is amend-
13 ed—

14 (1) by redesignating subsections (h) and (i) as
15 subsections (j) and (k), respectively; and

16 (2) by inserting after subsection (g) the fol-
17 lowing:

18 “(h) RISK MANAGEMENT PLANS.—Each manufac-
19 turer of a device that is critical to the public health, in-
20 cluding devices that are life-supporting, life-sustaining, or
21 intended for use in emergency medical care or during sur-
22 gery, shall develop, maintain, and, as appropriate, imple-
23 ment a redundancy risk management plan that identifies
24 and evaluates risks to the supply of the device, as applica-

1 ble, for each establishment in which such device is manu-
2 factured. A risk management plan under this subsection—

3 “(1) may identify and evaluate risks to the sup-
4 ply of more than 1 device manufactured at the same
5 establishment; and

6 “(2) shall be subject to inspection and copying
7 by the Secretary pursuant to section 704 or at the
8 request of the Secretary.”.

9 (b) REPORT.—Not later than 2 years after the date
10 of enactment of this Act, and annually for 4 years there-
11 after, the Secretary of Health and Human Services shall
12 prepare and submit to the Committee on Health, Edu-
13 cation, Labor, and Pensions of the Senate and the Com-
14 mittee on Energy and Commerce of the House of Rep-
15 resentatives a report on the use of information manufac-
16 turers submit pursuant to section 506J of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 356j) and ap-
18 plicable guidance issued with respect to such section.

19 **SEC. 516. PREVENTING MEDICAL DEVICE SHORTAGES.**

20 (a) NOTIFICATIONS.—Section 506J of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as
22 amended by section 515, is further amended—

23 (1) in the flush text at the end of subsection
24 (a), by inserting “or of any other circumstance that
25 is likely to lead to a meaningful disruption in the

1 supply of the device or a shortage of the device and
2 other devices that could reasonably be substituted
3 for that device in the United States” before the pe-
4 riod;

5 (2) in subsection (f), by inserting “or (i)” after
6 “subsection (a)”; and

7 (3) by inserting after subsection (h), as added
8 by section 515, the following:

9 “(i) **ADDITIONAL NOTIFICATIONS.**—The Secretary
10 may receive notifications from a manufacturers of a device
11 that is life-supporting, life-sustaining, or intended for use
12 in emergency medical care or during surgery, or any other
13 device the Secretary determines to be critical to the public
14 health, pertaining to a permanent discontinuance in the
15 manufacture of the device (except for any discontinuance
16 as a result of an approved modification of the device) or
17 an interruption of the manufacture of the device that is
18 likely to lead to a meaningful disruption in the supply of
19 that device in the United States, and the reasons for such
20 discontinuance or interruption.”.

21 (b) **GUIDANCE ON VOLUNTARY NOTIFICATIONS OF**
22 **DISCONTINUANCE OR INTERRUPTION OF DEVICE MANU-**
23 **FACTURE.**—Not later than 1 year after the date of enact-
24 ment of this Act, the Secretary shall issue draft guidance
25 to facilitate voluntary notifications under subsection (i) of

1 section 506J of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 356j), as added by subsection (a). Such
3 guidance shall include a description of circumstances in
4 which a voluntary notification under such subsection (i)
5 may be appropriate, recommended timeframes within
6 which sponsors should submit such a notification, the
7 process for receiving such notifications, and actions the
8 Secretary may take to mitigate or prevent a shortage re-
9 sulting from a discontinuance or interruption in the manu-
10 facture of a device for which such notification is received.
11 The Secretary shall issue final guidance not later than 1
12 year after the close of the comment period for the draft
13 guidance.

14 **SEC. 517. REMOTE RECORDS ASSESSMENTS FOR MEDICAL**
15 **DEVICES.**

16 (a) **FACTORY INSPECTION.**—Section 704(a)(4)(A) of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 374(a)(4)(A)) is amended—

19 (1) in the first sentence, by inserting “or de-
20 vice” after “processing of a drug”; and

21 (2) in the second sentence, by striking “shall
22 include” and all that follows through the period at
23 the end and inserting the following: “shall include—

24 “(A) a sufficient description of the records
25 requested; and

1 “(B) a rationale for requesting such infor-
2 mation in advance of, or in lieu of, an inspec-
3 tion.”.

4 (b) GUIDANCE.—Not later than 1 year after the date
5 of enactment of this Act, the Secretary shall issue draft
6 guidance describing circumstances in which the Secretary
7 intends to issue requests for records or other information
8 in advance of, or in lieu of, an inspection, processes for
9 responding to such requests electronically or in physical
10 form, and factors the Secretary intends to consider in eval-
11 uating whether such records are provided within a reason-
12 able timeframe, within reasonable limits, and in a reason-
13 able manner, accounting for resource and other limitations
14 that may exist, including for small businesses. The Sec-
15 retary shall issue final guidance not later than 1 year after
16 the close of the comment period for the draft guidance.

17 **SEC. 518. ADVANCED MANUFACTURING TECHNOLOGIES**
18 **DESIGNATION PILOT PROGRAM.**

19 Subchapter A of chapter V of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as
21 amended by section 506, is further amended by inserting
22 after section 506K the following:

1 **“SEC. 506L. ADVANCED MANUFACTURING TECHNOLOGIES**
2 **DESIGNATION PILOT PROGRAM.**

3 “(a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of this section, the Secretary shall ini-
5 tiate a pilot program under which persons may request
6 designation of an advanced manufacturing technology as
7 described in subsection (b).

8 “(b) DESIGNATION PROCESS.—The Secretary shall
9 establish a process for the designation under this section
10 of methods of manufacturing drugs, including biological
11 products, as advanced manufacturing technologies. A
12 method of manufacturing, including a combination of
13 manufacturing methods, is eligible for designation as an
14 advanced manufacturing technology if such method incor-
15 porates a novel technology, or uses an established tech-
16 nique or technology in a novel way, that will substan-
17 tially—

18 “(1) enhance drug quality; or

19 “(2) improve the manufacturing process for a
20 drug **【and maintain drug quality】**, including by—

21 “(A) reducing development time for a drug
22 using the designated manufacturing method; or

23 “(B) increasing or maintaining the supply
24 of—

1 “(i) a drug that is life-supporting,
2 life-sustaining, or of critical importance to
3 providing health care; or

4 “(ii) a drug that is on the drug short-
5 age list under section 506E.

6 “(c) EVALUATION OF AN ADVANCED MANUFAC-
7 TURING TECHNOLOGY.—

8 “(1) SUBMISSION.—A person who requests des-
9 ignation of a method of manufacturing as an ad-
10 vanced manufacturing technology under this section
11 shall submit to the Secretary data or information
12 demonstrating that the method of manufacturing
13 meets the criteria described in subsection (b) in a
14 particular context of use. A request for the designa-
15 tion may be made concurrently with, or at any time
16 after, the submission for an investigational use ex-
17 emption under section 505(i) of this Act or section
18 351(a)(3) of the Public Health Service Act. The Sec-
19 retary may facilitate the development and review of
20 such data or information by—

21 “(A) providing timely advice to, and inter-
22 active communication with, such person regard-
23 ing the development of the method of manufac-
24 turing; and

1 “(B) involving senior managers and experi-
2 enced staff of the Food and Drug Administra-
3 tion, as appropriate, in a collaborative, cross-
4 disciplinary review of the method of manufac-
5 turing, as applicable.

6 “(2) EVALUATION.—Not later than 180 cal-
7 endar days after the receipt of a request under para-
8 graph (1), the Secretary shall determine whether to
9 designate such method of manufacturing as an ad-
10 vanced manufacturing technology, in a particular
11 context of use, based on the data and information
12 submitted under paragraph (1) and the criteria de-
13 scribed in subsection (b).

14 “(d) DESIGNATION AS AN ADVANCED MANUFAC-
15 TURING TECHNOLOGY.—If the Secretary designates a
16 method of manufacturing as an advanced manufacturing
17 technology, the Secretary shall—

18 “(1) expedite the development and review of an
19 application submitted under section 505 of this Act
20 or section 351 of the Public Health Service Act, in-
21 cluding supplemental applications, for drugs that are
22 manufactured using a designated advanced manufac-
23 turing technology; and

24 “(2) allow the holder of an advanced technology
25 designation, or a person authorized by the advanced

1 manufacturing technology designation holder, to refer-
2 ence **【or rely upon】**, in an application submitted
3 under section 505 of this Act or section 351 of the
4 Public Health Service Act, including a supplemental
5 application, data and information about the des-
6 igned advanced manufacturing technology for use
7 in manufacturing drugs in the same context of use
8 for which the designation was granted.

9 “(e) IMPLEMENTATION AND EVALUATION OF AD-
10 VANCED MANUFACTURING TECHNOLOGIES PILOT.—

11 “(1) PUBLIC MEETING.—The Secretary shall
12 publish in the Federal Register a notice of a public
13 meeting, to be held not later than 180 days after the
14 date of enactment of this section, to discuss, and ob-
15 tain input and recommendations from relevant
16 stakeholders regarding—

17 “(A) the goals and scope of the pilot pro-
18 gram, and a suitable framework, procedures,
19 and requirements for such program; and

20 “(B) ways in which the Food and Drug
21 Administration will support the use of advanced
22 manufacturing technologies and other innova-
23 tive manufacturing approaches for drugs.

24 “(2) PILOT PROGRAM GUIDANCE.—

25 “(A) IN GENERAL.—The Secretary shall—

1 “(i) not later than 180 days after the
2 public meeting under paragraph (1), issue
3 draft guidance regarding the goals and im-
4 plementation of the pilot program under
5 this section; and

6 “(ii) not later than 2 years after the
7 date of enactment of this section, issue
8 final guidance regarding the implementa-
9 tion of such program.

10 “(B) CONTENT.—The guidance described
11 in subparagraph (A) shall address—

12 “(i) the process by which a person
13 may request a designation under sub-
14 section (b);

15 “(ii) the data and information that a
16 person requesting such a designation is re-
17 quired to submit under subsection (c), and
18 how the Secretary intends to evaluate such
19 submissions;

20 “(iii) the process to expedite the de-
21 velopment and review of applications under
22 subsection (d); and

23 “(iv) the criteria described in sub-
24 section (b) for eligibility for such a des-
25 ignation.

1 “(3) REPORT.—Not later than 3 years after the
2 date of enactment of this section and annually there-
3 after, the Secretary shall submit to the Committee
4 on Health, Education, Labor, and Pensions of the
5 Senate and the Committee on Energy and Com-
6 merce of the House of Representatives a report con-
7 taining a description and evaluation of the pilot pro-
8 gram being conducted under this section, including
9 the types of innovative manufacturing approaches
10 supported under the program.

11 “(f) SUNSET.—The Secretary may not carry out a
12 pilot program initiated under this section after October
13 1, 2027.”.

14 **SEC. 519. TECHNICAL CORRECTIONS.**

15 (a) TECHNICAL CORRECTIONS TO THE CARES
16 ACT.—Division A of the CARES Act (Public Law 116–
17 136) is amended—

18 (1) in section 3111(1), by striking “in para-
19 graph (1)” and inserting “in the matter preceding
20 paragraph (1)”;

21 (2) in section 3112(d)(1), by striking “and sub-
22 paragraphs (A) and (B)” and inserting “as subpara-
23 graphs (A) and (B)”;

1 (3) in section 3112(e), by striking “Federal
2 Food, Drug, Cosmetic Act” and inserting “Federal
3 Food, Drug, and Cosmetic Act”.

4 (b) TECHNICAL CORRECTIONS TO THE FEDERAL
5 FOOD, DRUG, AND COSMETIC ACT RELATED TO THE
6 CARES ACT.—

7 (1) SECTION 506C.—Section 506C(a) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 356c(a)) is amended, in the flush text at the end, by
10 striking the second comma after “in the United
11 States”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by paragraph (1) shall take effect as if included in
14 section 3112 of division A of the CARES Act (Pub-
15 lic Law 116–136).

16 (c) OTHER TECHNICAL CORRECTION TO THE FED-
17 ERAL FOOD, DRUG, AND COSMETIC ACT.—Section
18 505B(f)(6)(I) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355c(f)(6)(I)) is amended by striking
20 “subsection (a)(3)(B)” and inserting “subsection
21 (a)(4)(C)”.