117TH CONGRESS
2D SESSION

S. 3799

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

IN THE SENATE OF THE UNITED STATES

MARCH 10 (legislative day, MARCH 7), 2022

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

TITLE I—STRENGTHENING FEDERAL AND STATE PREPAREDNESS

Subtitle A—Federal Leadership and Accountability

SEC. 101. COMPREHENSIVE REVIEW OF THE COVID–19 RESPONSE.

(a) ESTABLISHMENT OF TASK FORCE.—There is established in the legislative branch a task force to be known as the ''National Task Force on the Response of the United States to the COVID–19 Pandemic'' (referred to in this section as the ''Task Force'').

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

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

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

(B) the ongoing Federal, State, local, and territorial responses in the United States, including the activities, policies, and decisions of the Trump Administration and the Biden Administration;

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

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

(2) build upon existing or ongoing evaluations and avoid unnecessary duplication, by reviewing the findings, conclusions, and recommendations of other appropriate task forces, committees, commissions, or entities established by other public or nonprofit private entities related to the United States' preparedness for, and response to, the COVID–19 pandemic;

(3) identify gaps in public health preparedness and medical response policies, processes, and activities, including disparities in COVID–19 infection and mortality rates among people of color, older

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

(4) submit a report to the President and to Congress on its findings, conclusions, and recommendations to improve the United States preparedness for, and response to, future public health emergencies, including a public health emergency resulting from an emerging infectious disease.

(c) COMPOSITION OF TASK FORCE; MEETINGS.—

(1) MEMBERS.—The Task Force shall be composed of 12 members, of whom—

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

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

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

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

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

(F) 1 member shall be appointed by the minority leader of the House of Representatives;

(G) 2 members shall be appointed by the chair of the Committee on Energy and Commerce of the House of Representatives; and

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

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

(3) QUALIFICATIONS.—

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

(B) NONGOVERNMENTAL APPOINTEES.—An individual appointed to the Task Force may

not be an officer or employee of the Federal Government or any State, local, Tribal, or territorial government.

(C) QUALIFICATIONS.—It is the sense of Congress that individuals appointed to the Task Force should be highly qualified citizens of the United States. Members appointed under paragraph (1) may include individuals with expertise in—

(i) public health, health disparities and at-risk populations, medicine, and related fields;

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

(iii) research regarding, or the development, manufacturing, distribution, and regulation of, medical products;

(iv) national security and foreign relations, including global health; and

(v) commerce, including transportation, supply chains, and small business.

(4) DEADLINE FOR APPOINTMENT.—All members of the Task Force shall be appointed not later than 90 days after the date of enactment of this Act.

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

(6) QUORUM; VACANCIES.—

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

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

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

(1) conduct a review that—

(A) examines the initial outbreak of the SARS–CoV–2 virus in Wuhan, China, including—

(i) engaging with willing partner governments and global experts;

(ii) seeking access to relevant records; and

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

(B) examines the United States preparation for, and response to, the COVID–19 pandemic, including—

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

(ii) relevant actions taken by, and coordination between, Federal, State, local, Tribal, and territorial governments, nongovernmental organizations, and international organizations on preparedness and response efforts, including coordination be-

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

(I) initial response in the United States;

(II) response during the Trump Administration; and

(III) ongoing response during the Biden Administration;

(iii) communication of public health and scientific information related to the COVID–19 pandemic, including processes for the development, approval, and dissemination of Federal public health and other relevant public health or scientific guidance;

(iv) actions taken to support the development, manufacturing, and distribution of medical countermeasures and related medical supplies to prevent, detect, and treat COVID–19; and

(C) may include assessments relating to—

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

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

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

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

(v) containment and mitigation measures related to domestic and international travel in response to COVID–19; and

(vi) the impact of the COVID–19 pandemic and related mitigation efforts on hard-to-reach and at-risk or underserved populations, including related health disparities;

(2) identify, review, and evaluate the lessons learned from the COVID–19 pandemic, including activities to prepare for, and respond to, future potential pandemics and related public health emergencies; and

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

(e) POWERS OF TASK FORCE.—

(1) HEARINGS.—The Task Force may—

(A) hold such hearings and sit and act at such times and places, take such testimony, receive such evidence as determined by the Chair and Vice Chair, and administer such oaths as the Task Force or a designated member, as determined by the Chair or Vice Chair, may determine advisable to be necessary to carry out the functions of the Task Force; and

(B) subject to paragraph (2)(A), require, by subpoena or otherwise, the attendance and testimony of such witnesses and the production of such books, records, correspondence, memoranda, papers, and documents, as the person described in paragraph (2)(A)(i) may determine advisable.

(2) SUBPOENAS.—

(A) ISSUANCE.—

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

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

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

(ii) SIGNATURE.—Subpoenas issued under this subsection may be issued under the signature of the Chair or any member designated by a majority of the Task Force, and may be served by any person designated by the Chair or by a member designated by agreement of the majority of the Task Force.

(B) ENFORCEMENT.—In the case of contumacy or failure to obey a subpoena issued under subsection, the United States district court for the judicial district in which the subpoenaed person resides, is served, or may be found, or where the subpoena is returnable, may issue an order requiring such person to appear at any designated place to testify or to produce documentary or other evidence. Any failure to obey the order of the court may be punished by the court as a contempt of that court.

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

(4) INFORMATION FROM FEDERAL AGENCIES.—

(A) IN GENERAL.—The Task Force may access from any executive department, bureau, agency, board, commission, office, independent establishment, or instrumentality of the Federal Government, such information, documents, suggestions, estimates, and statistics as the Task Force considers necessary to carry out this section.

(B) PROVISION OF INFORMATION.—On written request of the Chair, each department, bureau, agency, board, commission, office, independent establishment, or instrumentality shall, to the extent authorized by law, provide such information to the Task Force.

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

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

(5) ASSISTANCE FROM FEDERAL AGENCIES.—

(A) GENERAL SERVICES ADMINISTRATION.—On request of the Chair and Vice Chair, the Administrator of General Services Administration shall provide to the Task Force, on a reimbursable basis, administrative support and other assistance necessary for the Task Force to carry out its duties.

(B) OTHER DEPARTMENTS AND AGENCIES.—In addition to the assistance provided for in subparagraph (A), departments and agencies of the United States may provide to the Task Force such assistance as such departments and agencies may determine advisable and as authorized by law.

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

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

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

(C) the value of such donation; and

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

(7) POSTAL SERVICES.—The Task Force may use the United States mails in the same manner and under the same conditions as a department or agency of the United States.

(f) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—

(1) IN GENERAL.—The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Task Force.

(2) PUBLIC MEETINGS AND RELEASE OF PUBLIC VERSIONS OF REPORTS.—The Task Force shall—

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

(B) release public versions of the reports required under paragraph (1) and (2) of subsection (j).

(3) PUBLIC HEARINGS.—Any public hearings of the Task Force shall be conducted in a manner consistent with the protection of information provided

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

(g) STAFF OF TASK FORCE.—

(1) IN GENERAL.—

(A) APPOINTMENT AND COMPENSATION.—The Chair of the Task Force, in agreement with the Vice Chair, in accordance with rules agreed upon by the Task Force, may appoint and fix the compensation of a staff director and such other personnel as may be necessary to enable the Task Force to carry out its functions, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, except that no rate of pay fixed under this subsection may exceed the equivalent of that payable for a position at level V of the Executive Schedule under section 5316 of title 5, United States Code.

(B) PERSONNEL AS FEDERAL EMPLOYEES.—

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

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

(2) DETAILEES.—Upon request of the Chair and Vice Chair of the Task Force, the head of any executive department, bureau, agency, board, commission, office, independent establishment, or instrumentality of the Federal Government employee may detail, without reimbursement, any of its personnel to the Task Force to assist in carrying out its duties under this section. Any such detailee shall be without interruption or loss of civil service status or privilege.

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

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

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

(i) SECURITY CLEARANCES FOR TASK FORCE MEMBERS AND STAFF.—The appropriate Federal agencies or departments shall cooperate with the Task Force in expeditiously providing to the Task Force members and staff appropriate security clearances, consistent with existing procedures and requirements. No person shall be provided with access to classified information under this section without the appropriate security clearances.

(j) REPORTS OF TASK FORCE; TERMINATION.—

(1) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Task Force shall submit to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives an interim report containing such findings, conclusions, and recommendations as have been agreed to by 8

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

(2) FINAL REPORT.—

(A) IN GENERAL.—Not later than 18 months after the date on which the last member of the Task Force is appointed, the Task Force shall submit to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a final report containing such findings, conclusions, and recommendations as have been agreed to by 8 members of the Task Force. The final report shall be made available online in a manner that does not compromise national security.

(B) EXTENSIONS.—

(i) IN GENERAL.—The submission and publication of the final report, as described in subparagraph (A), may be delayed by 6 months upon the agreement of 8 members of the Task Force.

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

on Health, Education, Labor, and Pensions of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the public of any extension granted under clause (i).

(C) SPECIAL RULES AND CONSIDERATIONS.—

(i) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing the Task Force to publicly disclose information otherwise prohibited from disclosure by law.

(ii) SPECIAL TIMING CONSIDERATIONS.—Notwithstanding any other provision of this section, the Task Force shall not publish or make available any interim or final report during the during the 60-day periods ending November 8, 2022, and November 5, 2024.

(3) TERMINATION.—

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

(B) ADMINISTRATIVE ACTIVITIES BEFORE TERMINATION.—The Task Force may use the 60-day period referred to in subparagraph (A) for the purpose of concluding its activities, including providing testimony to committees of Congress concerning its reports and disseminating the final report.

(k) FUNDING.—

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

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

SEC. 102. APPOINTMENT AND AUTHORITY OF THE DIRECTOR OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

"SEC. 305. APPOINTMENT AND AUTHORITY OF THE DIRECTOR OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

''(a) IN GENERAL.—The Centers for Disease Control and Prevention (referred to in this section as the 'CDC') shall be headed by the Director of the Centers for Disease Control and Prevention (referred to in this section as the 'Director'), who shall be appointed by the President, by and with the advice and consent of the Senate. Such individual shall also serve as the Administrator of the Agency for Toxic Substances and Disease Registry consistent with section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act. The Director shall perform functions provided for in subsection (b) and such other functions as the Secretary may prescribe.

''(b) FUNCTIONS.—The Secretary, acting through the Director, shall—

''(1) implement and exercise applicable authorities and responsibilities provided for in this Act or other applicable law related to the investigation, detection, identification, prevention, or control of diseases or conditions to preserve and improve public health domestically and globally and address injuries and occupational and environmental hazards, as appropriate;

''(2) be responsible for the overall direction of the CDC and for the establishment and implementation of policies related to the management and operation of programs and activities within the CDC;

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

''(4) support, in consultation with the heads of such centers, institutes, and offices, program coordination across such centers, institutes, and offices, including through priority setting reviews and the development of strategic plans, to reduce unnecessary duplication and encourage collaboration between programs;

''(5) oversee the development, implementation, and updating of the strategic plan established pursuant to subsection (c);

''(6) ensure that appropriate strategic planning, including the use of performance metrics, is conducted by such centers, institutes, and offices to facilitate and improve CDC programs and activities;

''(7) communicate, including through convening annual meetings, with public and private entities regarding relevant public health programs and activities, and, as applicable, the strategic plan established pursuant to subsection (c).

''(c) STRATEGIC PLAN.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the PREVENT Pandemics Act, and at least every 4 years thereafter, the Director shall develop and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and post on the website of the CDC, a coordinated strategy to provide strategic direction and facilitate collaboration across the centers, institutes, and offices within the CDC. Such strategy shall be known as the 'CDC Strategic Plan'.

''(2) REQUIREMENTS.—The CDC Strategic Plan shall—

''(A) identify strategic priorities and objectives related to—

''(i) preventing, reducing, and eliminating the spread of communicable and noncommunicable diseases or conditions, and addressing injuries, and occupational and environmental hazards;

''(ii) supporting the efforts of State, local, and Tribal health departments to

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

"(iii) containing, mitigating, and ending disease outbreaks;

"(iv) enhancing global and domestic public health capacity, capabilities, and preparedness, including public health data, surveillance, workforce, and laboratory capacity and safety; and

"(v) other priorities, as established by the Director;

"(B) describe the capacity and capabilities necessary to achieve the priorities and objectives under subparagraph (A), and progress towards achieving such capacity and capabilities, as appropriate; and

"(C) include a description of how the CDC Strategic Plan incorporates—

"(i) strategic communications;

"(ii) partnerships with private sector entities, and State, local, and Tribal health departments, and other public sector entities, as appropriate; and

"(iii) coordination with other agencies and offices of the Department of Health

and Human Services and other Federal departments and agencies, as appropriate.

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

''(d) APPEARANCES BEFORE CONGRESS.—

''(1) IN GENERAL.—Each fiscal year, the Director shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings on topics such as—

''(A) support for State, local, and Tribal public health preparedness and responses to any recent or ongoing public health emergency, including—

''(i) any objectives, activities, or initiatives that have been carried out, or are planned, by the Director to prepare for, or respond to, the public health emergency, including relevant strategic communications or partnerships and any gaps or chal-

lenges identified in such objectives, activities, or initiatives;

''(ii) any objectives and planned activities for the upcoming fiscal year to address gaps in, or otherwise improve, State, local, and Tribal public health preparedness; and

''(iii) other potential all-hazard threats that the Director is preparing to address;

''(B) activities related to public health and functions of the Director described in subsection (b); and

''(C) updates on other relevant activities supported or conducted by the CDC, or in collaboration or coordination with the heads of other Federal departments, agencies, or stakeholders, as appropriate.

''(2) CLARIFICATIONS.—

''(A) WAIVER AUTHORITY.—The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable

fiscal year with respect to the applicable Committee.

''(B) SCOPE OF REQUIREMENTS.—The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Director at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1).

''(3) CLOSED HEARINGS.—Information that is not appropriate for disclosure during an open hearing under paragraph (1) in order to protect national security may instead be discussed in a closed hearing that immediately follows the open hearing.''.

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

SEC. 103. ADDITIONAL PROVISIONS RELATED TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

"SEC. 305A. ADDITIONAL PROVISIONS RELATED TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

''(a) APPOINTMENTS.—

''(1) IN GENERAL.—Unless otherwise specified in statute, the heads of the centers or institutes of the Centers for Disease Control and Prevention shall be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this section as the 'Director'). Each such individual shall be appointed for 5 years.

''(2) REAPPOINTMENTS.—At the end of a 5-year term, an individual appointed under paragraph (1) shall be reappointed in accordance with standards applicable to the relevant appointment mechanism and as determined by the Secretary, as applicable.

''(3) NO LIMIT ON TERMS.—There shall be no limit on the number of terms that any individual appointed under this subsection may serve.

''(4) VACANCIES.—If the position of a head of a center or institute described in paragraph (1) becomes vacant before the end of a term, the head of such center or institute appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

''(5) CURRENT POSITIONS AND EXEMPTIONS.—

''(A) IN GENERAL.—Each such individual who is serving on the date of enactment of the PREVENT Pandemics Act shall be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

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

''(6) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director to terminate the appointment of a head of a center or institute described in paragraph (1) before the expiration of such individual's 5-year term.

''(7) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the Centers for Disease Control and Prevention and its components, including compliance with relevant legal requirements.

''(b) OTHER TRANSACTIONS.—

''(1) IN GENERAL.—In carrying out activities of the Centers for Disease Control and Prevention, the Director may enter into transactions other than a contract, grant, or cooperative agreement for purposes of biosurveillance, infectious disease modeling, and public health preparedness and response, including related research.

''(2) WRITTEN DETERMINATION.—With respect to a project that is expected to cost the Centers for Disease Control and Prevention more than $5,000,000, the Director may exercise the authority under paragraph (1) only upon a written determination by the Assistant Secretary for Financial Resources of the Department of Health and Human Services, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this paragraph may not be delegated.

''(3) GUIDELINES.—The Director, in consultation with the Secretary, shall establish guidelines regarding the use of the authority under paragraph (1). Such guidelines shall include auditing requirements.''.

SEC. 104. PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE COORDINATION.

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

(1) in paragraph (2)—

(A) in subparagraph (E), by striking ''and'' at the end;

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

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

''(F) support the initial deployment and distribution of contents of the Strategic National Stockpile, as appropriate; and''; and

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

''(A) the expenditures made from the Public Health Emergency Fund in such fiscal year, including—

''(i) the amount obligated;

''(ii) the recipient or recipients of such obligated funds;

''(iii) the specific response activities such obligated funds will support; and

''(iv) the declared or potential public health emergency for which such funds were obligated; and''.

(b) IMPROVING PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE COORDINATION.—

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

''(c) COORDINATION WITH FEDERAL AGENCIES.—In leading the Federal public health and medical response to a declared or potential public health emergency, consistent with this section, the Secretary shall coordinate with, and may request support from, other Federal departments and agencies, as appropriate in order to carry out necessary activities and leverage the expertise of such departments and agencies, which may include the provision of assistance at the direction of the Secretary related to supporting the public health and medical response for States, localities, and Tribes.''.

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

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

work and other applicable provisions of law, assist the Secretary in carrying out the functions under section 2801'' before the period; and

(B) in paragraph (4)—

(i) in subparagraph (E) by striking ''the actions necessary to overcome these obstacles.'' and inserting ''recommend actions necessary to overcome these obstacles, such as—

''(i) improving coordination with relevant Federal officials;

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

''(iii) coordinating efforts to support or establish new capabilities, as appropriate.''; and

(ii) in subparagraph (G)—

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

(II) in the matter preceding subclause (I), as so redesignated—

(aa) by inserting ''each year, including national-level and State-level full-scale exercises not less than once every 5 years'' after ''operational exercises''; and

(bb) by striking ''exercises based on—'' and inserting ''exercises—

''(i) based on'';

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

(IV) by adding at the end the following:

''(ii) that assess the ability of the Strategic National Stockpile, as appropriate, to provide medical countermeasures, medical products, and other supplies, including ancillary medical supplies, to support the response to a public health emergency or potential public health emergency, including a threat that requires the large-scale and simultaneous deployment of stockpiles and a long-term public health and medical response; and

''(iii) conducted in coordination with State and local health officials.''.

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

''(g) APPEARANCES BEFORE CONGRESS.—

''(1) IN GENERAL.—Each fiscal year, the Assistant Secretary for Preparedness and Response shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings, on topics such as—

''(A) coordination of Federal activities to prepare for, and respond to, public health emergencies;

''(B) activities and capabilities of the Strategic National Stockpile, including whether, and the degree to which, recommendations made pursuant to section 2811–1(c)(1)(A) have been met;

''(C) support for State, local, and Tribal public health and medical preparedness;

''(D) activities implementing the countermeasures budget plan described under subsection (b)(7), including—

''(i) any challenges in meeting the full range of identified medical countermeasure needs; and

''(ii) progress in supporting advanced research, development, and procurement of medical countermeasures, pursuant to subsection (b)(3);

''(E) the strategic direction of, and activities related to, the sustainment of manufacturing surge capacity and capabilities for medical countermeasures pursuant to section 319L and the distribution and deployment of such countermeasures;

''(F) any additional objectives, activities, or initiatives that have been carried out or are planned by the Assistant Secretary for Preparedness and Response and associated challenges, as appropriate;

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

being addressed, through the activities described in subparagraphs (A) through (F); and

''(H) objectives, activities, or initiatives related to the coordination and consultation required under subsections (b)(4)(H) and (b)(4)(I), in a manner consistent with paragraph (3), as appropriate.

''(2) CLARIFICATIONS.—

''(A) WAIVER AUTHORITY.—The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable fiscal year with respect to the applicable Committee.

''(B) SCOPE OF REQUIREMENTS.—The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Assistant Secretary at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1).

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

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

''(d) ANNUAL REPORT ON EMERGENCY RESPONSE AND PREPAREDNESS.—The Secretary shall submit a written report each fiscal year to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, containing—

''(1) updated information related to an assessment of the response to any public health emergency declared, or otherwise in effect, during the previous fiscal year;

''(2) findings related to drills and operational exercises completed in the previous fiscal year pursuant to section 2811(b)(4)(G);

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

logical, and nuclear threats, including emerging infectious diseases; and

''(4) any challenges in preparing for or responding to such threats, as appropriate.''.

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

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

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

(B) the manner in which specific capabilities of each such Federal department or agency may be utilized under such interagency agreements;

(C) the frequency with which such interagency agreements have been utilized;

(D) gaps, if any, in interagency agreements that prevent the Secretary from carrying

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

(E) barriers, if any, to establishing or utilizing such interagency agreements; and

(F) recommendations, if any, on the ways in which such interagency agreements can be improved to address the gaps and barriers identified under subparagraphs (D) and (E);

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

(3) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the reviews under paragraphs (1) and (2), including related recommendations, as applicable.

SEC. 105. STRENGTHENING PUBLIC HEALTH COMMUNICATION.

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

''(b) PUBLIC HEALTH INFORMATION AND COMMUNICATIONS ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the Public Health Information and Communications Advisory Committee (referred to in this subsection as the 'Advisory Committee').

''(2) DUTIES.—The Advisory Committee shall make recommendations to the Secretary and report on—

''(A) critical aspects of communication and dissemination of scientific and evidence-based public health information during public health emergencies, including—

''(i) the role and impact of misinformation on the response to such public health emergencies;

''(ii) the role of risk communication before and during such public health emergencies; and

''(iii) other relevant factors, as the Secretary determines appropriate;

''(B) information from academic institutions, community-based organizations, and other nongovernmental organizations related to evidence-based or evidence-informed strategies

and best practices to effectively communicate and disseminate such information;

''(C) strategies to improve communication and dissemination of scientific and evidence-based public health information to the public, to improve such communication between Federal, State, local, and Tribal health officials, and, as appropriate, to address misinformation during public health emergencies, including strategies to—

''(i) identify the most effective methods for the dissemination of information during a public health emergency, with consideration of the needs of at-risk populations;

''(ii) determine best practices and communicate information to populations that may be impacted by such misinformation; and

''(iii) adapt approaches for the dissemination of information, as appropriate, to address emerging trends related to misinformation.

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

''(A) appropriate Federal officials, appointed by the Secretary, who shall serve as nonvoting members; and

''(B) individuals, appointed by the Secretary, with expertise in public health (including individuals with experience in State, local, and Tribal health departments), medicine, communications, related technology, psychology, mental health and substance use disorders, national security, and other areas, as the Secretary determines appropriate, who shall serve as voting members.

''(4) DISSEMINATION.—The Secretary shall review the recommendations of the Advisory Committee and, not later than 180 days after receipt of the report under paragraph (2), shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing any actions planned by the Secretary related to the communication and dissemination of scientific and evidence-based public health information, including addressing misinformation, as appropriate.

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

SEC. 106. OFFICE OF PANDEMIC PREPAREDNESS AND RESPONSE POLICY.

(a) IN GENERAL.—There is established in the Executive Office of the President an Office of Pandemic Preparedness and Response Policy (referred to in this section as the ''Office''), which shall be headed by a Director (referred to in this section as the ''Director'') appointed by the President and who shall be compensated at the rate provided for level II of the Executive Schedule in section 5313 of title 5, United States Code. The President is authorized to appoint not more than 2 Associate Directors, who shall be compensated at a rate not to exceed that provided for level III of the Executive Schedule in section 5314 of such title. Associate Directors shall perform such functions as the Director may prescribe.

(b) FUNCTIONS OF THE DIRECTOR.—The primary function of the Director is to provide advice, within the Executive Office of the President, on pandemic preparedness and response policy, and support strategic coordination and communication with respect to relevant activities across the Federal Government. In addition to such other functions and activities as the President may assign, the

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

(1) serve as the principal advisor to the President on all matters related to pandemic preparedness and response policy and make recommendations to the President regarding pandemic and other biological threats that may impact national security;

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

(A) providing strategic direction to the heads of applicable Federal departments, agencies, and offices, including—

(i) the establishment, implementation, prioritization, and assessment of policy goals and objectives across the Executive Office of the President and such departments, agencies, and offices;

(ii) supporting the assessment and clarification of roles and responsibilities related to such Federal activities; and

(iii) supporting the development and implementation of metrics and performance measures to evaluate the extent to

which applicable activities meet such goals and objectives;

(B) providing, in consultation with the Secretary of Health and Human Services and the heads of other relevant Federal departments, agencies, and offices, leadership with respect to the National Biodefense Strategy and related activities pursuant to section 1086 of the National Defense Authorization Act for Fiscal Year 2017 (6 U.S.C. 104) and section 363 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (6 U.S.C. 105);

(C) facilitating coordination and communication between such Federal departments, agencies, and offices to improve preparedness for, and response to, such threats;

(D) ensuring that the authorities, capabilities, and expertise of each such department, agency, and office are appropriately leveraged to facilitate the whole-of-Government response to such threats;

(E) overseeing coordination of Federal efforts to prepare for and support the production, supply, and distribution of relevant medical

products and supplies during a response to a pandemic or other biological threat, as applicable and appropriate, including supporting Federal efforts to assess any relevant vulnerabilities in the supply chain of such products and supplies;

(F) overseeing coordination of Federal efforts for the basic and advanced research, development, manufacture, and procurement of medical countermeasures, including by—

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

(ii) promoting coordination between the medical countermeasure research, development, and procurement activities of respective Federal departments and agencies, including to advance the discovery and development of new medical products and technologies;

(G) convening heads of Federal departments and agencies, as appropriate, on topics related to capabilities to prepare for, and respond to, such threats;

(H) assessing and advising on international cooperation in preparing for, and responding to, such threats to advance the national security objectives of the United States; and

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

(i) drills and operational exercises conducted pursuant to applicable provisions of law; and

(ii) Federal after-action reports developed following such drills and exercises or a response to a pandemic or other biological threat;

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

(4) consult with the Director of the Office of Management and Budget and other relevant officials within the Executive Office of the President, including the Assistant to the President for National Security Affairs and the Director of the Office of Science and Technology Policy, regarding activities related to preparing for, and responding to, such threats and relevant research and emerging technologies that may advance the biosecurity and preparedness and response goals of the Federal Government;

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

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

(c) SUPPORT FROM OTHER AGENCIES.—Each department, agency, and instrumentality of the executive branch of the Federal Government, including any independent agency, is authorized to support the Director by providing the Director such information as the Director

determines necessary to carry out the functions of the Director under this section.

(d) PREPAREDNESS OUTLOOK REPORT.—

(1) IN GENERAL.—Within its first year of operation, the Director, in consultation with the heads of relevant Federal departments and agencies and other officials within the Executive Office of the President, shall through a report submitted to the President and made available to the public, to the extent practicable, identify and describe situations and conditions which warrant special attention within the next 5 years, involving current and emerging problems of national significance related to pandemic or other biological threats, and opportunities for, and the barriers to, the research, development, and procurement of medical countermeasures to adequately respond to such threats.

(2) REVISIONS.—The Office shall revise the report under paragraph (1) not less than once every 5 years and work with relevant Federal officials to address the problems, barriers, opportunities, and actions identified under this report through the development of the President's Budgets and programs.

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

that will meet on a regular basis to evaluate national biosecurity and pandemic preparedness issues and make recommendations to the heads of applicable Federal departments, agencies and offices. The working group shall consist of representatives from—

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

(2) the Department of Health and Human Services;

(3) the Department of Homeland Security;

(4) the Department of Defense;

(5) the Office of Management and Budget; and

(6) other Federal Departments and agencies.

(f) ADDITIONAL FUNCTIONS OF THE DIRECTOR.—The Director, in addition to the other duties and functions set forth in this section—

(1) shall—

(A) serve as a member of the Domestic Policy Council and the National Security Council;

(B) serve as a member of the Intergovernmental Science, Engineering, and Technology Advisory Panel under section 205(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976 (42 U.S.C.

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

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

(D) use for administrative purposes, on a reimbursable basis, the available services, equipment, personnel, and facilities of Federal, State, and local agencies; and

(E) at the President's request, perform such other duties and functions and enter into contracts and other arrangements for studies, analyses, and related services with public or private entities, as applicable and appropriate; and

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

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

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

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

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

(4) direct, with the concurrence of the Secretary of a department or head of an agency, the temporary reassignment within the Federal Government of personnel employed by such department or agency, in order to carry out the functions of the Office.

(h) PREPAREDNESS REVIEW AND REPORT.—The Director, in consultation with the heads of applicable Federal departments, agencies, and offices, shall—

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

tion reports to identify gaps and inefficiencies related to pandemic preparedness and response;

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

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

(B) the roles and responsibilities of the Federal Government in preparing for, and responding to, such threats;

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

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

(E) current and planned activities to update Federal strategies, policies, and procedures to address such findings, consistent with applicable laws and the National Response Framework;

(F) current and planned activities to support the development of expertise within the

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

(G) opportunities to improve Federal preparedness and response capacities and capabilities through the use of current and emerging technologies.

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

(j) CONFORMING AMENDMENTS.—

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

(A) in the second sentence of subsection (a), by striking ''shall serve as chair'' and inserting ''and the Director of the Office of Pandemic Preparedness and Response Policy shall serve as co-chairs''; and

(B) in subsection (b)—

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

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

''(10) The Director of the Office of Pandemic Preparedness and Response Policy.''.

(2) Section 101(c)(1) of the National Security Act of 1947 (50 U.S.C. 3021(c)(1)) is amended by inserting ''the Director of the Office of Pandemic Preparedness and Response Policy'' after ''Treasury,''.

(3) The National Science and Technology Policy, Organization, and Priorities Act of 1976 (42 U.S.C. 6601 et seq.) is amended—

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

(i) by striking ''and (C)'' and inserting ''(C)''; and

(ii) by striking the period at the end and inserting ''; and (D) the Director of the Office of Pandemic Preparedness and Response Policy.''; and

(B) in section 401(b) (42 U.S.C. 6651(b)), by inserting '', the Director of the Office of Pandemic Preparedness and Response Policy,'' after ''Technology Policy''.

Subtitle B—State and Local Readiness

SEC. 111. IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.

(a) IN GENERAL.—Section 319C–1(b)(2) of the Public Health Service Act (42 U.S.C. 247d–3a(b)(2)) is amended—

(1) in subparagraph (A)—

(A) in clause (vii), by inserting ''during and'' before ''following a public health emergency'';

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

''(viii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State education agencies (as defined in section 8101 of the Elementary and Secondary Education Act of 1965), State child care lead agencies (designated under section 658D of the Child Care and Development Block Grant Act of 1990), and other relevant State agencies'';

(C) in clause (xi), by striking ''; and'' and inserting a semicolon;

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

(E) by inserting after clause (xi) the following:

''(xii) a description of how the entity will provide technical assistance to improve public health preparedness and response, as appropriate, to agencies or other entities that operate facilities within the entity's jurisdiction in which there is an increased risk of infectious disease outbreaks in the event of a public health emergency declared under section 319, such as residential care facilities, group homes, and other similar settings; and'';

(2) by redesignating subparagraphs (D) through (H) as subparagraphs (E) through (I), respectively; and

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

''(D) an assurance that the entity will require relevant staff to complete relevant preparedness and response trainings, including

trainings related to efficient and effective operation during an incident or event within an Incident Command System;''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall not apply with respect to any cooperative agreement entered into prior to the date of enactment of this Act.

SEC. 112. SUPPORTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES DURING PUBLIC HEALTH EMERGENCIES.

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

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

(2) by inserting after paragraph (23) the following:

''(24) support the continued access to, or availability of, mental health and substance use disorder services during, or in response to, a public health emergency declared under section 319, including in consultation with, as appropriate, the Assistant Secretary for Preparedness and Response and the heads of other relevant agencies, in preparing for, and responding to, a public health emergency;''.

(b) STRATEGIC PLAN.—Section 501(l)(4) of the Public Health Service Act (42 U.S.C. 290aa(l)(4)) is amended—

(1) in subparagraph (E), by striking ''and'' at the end;

(2) in subparagraph (F), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(G) specify a strategy to support the continued access to, or availability of, mental health and substance use disorder services, including to at-risk individuals (as defined in section 2802(b)(4)), during, or in response to, public health emergencies declared pursuant to section 319.''.

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

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

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

''(4) a description of the Administration's activities to support the continued provision of mental health and substance use disorder services, as appli-

cable, in response to public health emergencies declared pursuant to section 319;''; and

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

(A) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

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

''(D) relevant preparedness and response activities;''.

(d) ADVISORY COUNCILS.—Not later than 1 year after the date of enactment of this Act, the Assistant Secretary for Mental Health and Substance Use shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, reflecting the feedback of the advisory councils for the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, and the Center for Mental Health Services, pursuant to section 502 of the Public Health Service Act (42 U.S.C. 290aa–1), with recommendations to improve the continued provision of mental health and substance use disorder services during a public health emergency declared under section 319 of such Act (42 U.S.C. 247d), and the provision of such services as part of the

public health and medical response to such an emergency, consistent with title XXVIII of such Act (42 U.S.C. 300hh et seq.), including related to the capacity of the mental health and substance use disorder workforce and flexibilities provided to awardees of mental health and substance use disorder programs.

(e) GAO REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on programs and activities of the Substance Abuse and Mental Health Services Administration to support the provision of mental health and substance use disorder services and related activities during the COVID–19 pandemic, including the provision of such services as part of the medical and public health response to such pandemic. Such report shall—

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

Abuse and Mental Health Services Administration to support the response of such agency to the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d) with respect to COVID–19;

(2) describe the manner in which existing awardees of mental health and substance use disorder programs provided and altered delivery of services during such public health emergency, including information on the populations served by such awardees and any barriers faced in delivering services; and

(3) describe activities of the Substance Abuse and Mental Health Services Administration to support the response to such public health emergency, including through technical assistance, provision of services, and any flexibilities provided to such existing awardees, and any barriers faced in implementing such activities.

SEC. 113. TRAUMA CARE REAUTHORIZATION.

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

(1) in subsection (a)—

(A) in paragraph (3)—

(i) by inserting ''analyze,'' after ''compile,''; and

(ii) by inserting ''and medically underserved areas'' before the semicolon;

(B) in paragraph (4), by adding ''and'' after the semicolon;

(C) by striking paragraph (5); and

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

(2) by redesignating subsection (b) as subsection (c); and

(3) by inserting after subsection (a) the following:

''(b) TRAUMA CARE READINESS AND COORDINATION.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall support the efforts of States and consortia of States to coordinate and improve emergency medical services and trauma care during a public health emergency declared by the Secretary pursuant to section 319 or a major disaster or emergency declared by the President under section 401 or 501, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act. Such support may include—

''(1) developing, issuing, and updating guidance, as appropriate, to support the coordinated

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

''(2) disseminating, as appropriate, information on evidence-based or evidence-informed trauma care practices, taking into consideration emergency medical services and trauma care systems, including such practices identified through activities conducted under subsection (a) and which may include the identification and dissemination of performance metrics, as applicable and appropriate; and

''(3) other activities, as appropriate, to optimize a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, and emergency medical systems.''.

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

(1) by amending the section heading to read as follows: ''**GRANTS TO IMPROVE TRAUMA CARE IN RURAL AREAS**'';

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

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities for the purpose of carrying out research and demonstration projects to support the improvement of emergency medical services and trauma care in rural areas through the development of innovative uses of technology, training and education, transportation of seriously injured patients for the purposes of receiving such emergency medical services, access to prehospital care, evaluation of protocols for the purposes of improvement of outcomes and dissemination of any related best practices, activities to facilitate clinical research, as applicable and appropriate, and increasing communication and coordination with applicable State or Tribal trauma systems.

''(b) ELIGIBLE ENTITIES.—

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

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

(3) by adding at the end the following:

''(d) REPORTS.—An entity that receives a grant under this section shall submit to the Secretary such reports as the Secretary may require to inform administration of the program under this section.''.

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

(1) by amending the section heading to read as follows: ''**PILOT GRANTS FOR TRAUMA CENTERS**'';

(2) in subsection (a)—

(A) by striking ''not fewer than 4'' and inserting ''10'';

(B) by striking ''that design, implement, and evaluate'' and inserting ''to design, implement, and evaluate new or existing'';

(C) by striking ''emergency care'' and inserting ''emergency medical''; and

(D) by inserting '', and improve access to trauma care within such systems'' before the period;

(3) in subsection (b)(1), by striking subparagraphs (A) and (B) and inserting the following:

''(A) a State or consortia of States;

''(B) an Indian Tribe or Tribal organization (as defined in section 4 of the Indian Self-Determination and Education Assistance Act);

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

''(D) a consortium or partnership of non-profit Indian Health Service, Indian Tribal, and urban Indian trauma centers.'';

(4) in subsection (c)—

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

(i) by striking ''that proposes a pilot project'';

(ii) by striking ''an emergency medical and trauma system that—'' and inserting ''a new or existing emergency medical and trauma system. Such eligible entity shall use amounts awarded under this subsection to carry out 2 or more of the following activities:'';

(B) in paragraph (1) —

(i) by striking ''coordinates'' and inserting ''Strengthening coordination and communication''; and

(ii) by striking ''an approach to emergency medical and trauma system access throughout the region, including 9–1–1 Public Safety Answering Points and emergency medical dispatch;'' and inserting ''approaches to improve situational awareness and emergency medical and trauma system access, including distribution of patients during a mass casualty incident, throughout the region.'';

(C) in paragraph (2)—

(i) by striking ''includes'' and inserting ''Providing'';

(ii) by inserting ''support patient movement to'' after ''region to''; and

(iii) by striking the semicolon and inserting a period;

(D) in paragraph (3)—

(i) by striking ''allows for'' and inserting ''Improving''; and

(ii) by striking ''; and'' and inserting a period;

(E) in paragraph (4), by striking ''includes a consistent'' and inserting ''Supporting a consistent''; and

(F) by adding at the end the following:

''(5) Establishing, implementing, and disseminating, or utilizing existing, as applicable, evidence-based or evidence-informed practices across facilities within such emergency medical and trauma system to improve health outcomes, including such practices related to management of injuries, and the ability of such facilities to surge.

''(6) Conducting activities to facilitate clinical research, as applicable and appropriate.'';

(5) in subsection (d)(2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''the proposed'' and inserting ''the applicable emergency medical and trauma system'';

(ii) in clause (i), by inserting ''or Tribal entity'' after ''equivalent State office''; and

(iii) in clause (vi), by striking ''; and'' and inserting a semicolon;

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

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

''(B) for eligible entities described in subparagraph (C) or (D) of subsection (b)(1), a description of, and evidence of, coordination with the applicable State Office of Emergency Medical Services (or equivalent State Office) or applicable such office for a Tribe or Tribal organization; and'';

(6) in subsection (e)—

(A) in paragraph (1), by striking ''$1 for each $3'' and inserting ''$1 for each $5''; and

(B) by adding at the end the following:

''(3) WAIVER.—The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for a State, consortia of States, Indian Tribe or Tribal organization, or trauma center, if the Secretary determines that applying such matching requirement would result in serious hardship or an inability to carry out the purposes of the pilot program.'';

(7) in subsection (f), by striking ''population in a medically underserved area'' and inserting ''medically underserved population'';

(8) in subsection (g)—

(A) in the matter preceding paragraph (1), by striking ''described in'';

(B) in paragraph (2), by striking ''the system characteristics that contribute to'' and inserting ''opportunities for improvement, including recommendations for how to improve'';

(C) by striking paragraph (4);

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

(E) in paragraph (4), as so redesignated, by striking ''; and'' and inserting a semicolon;

(F) in paragraph (5), as so redesignated, by striking the period and inserting ''; and''; and

(G) by adding at the end the following:

''(6) any evidence-based or evidence-informed strategies developed or utilized pursuant to subsection (c)(5).''; and

(9) by amending subsection (h) to read as follows:

''(h) DISSEMINATION OF FINDINGS.—Not later than 1 year after the completion of the final project under subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the information contained in each report submitted pursuant to subsection (g) and any additional actions planned by the Secretary related to regionalized emergency care and trauma systems.''.

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

SEC. 114. ASSESSMENT OF CONTAINMENT AND MITIGATION OF INFECTIOUS DISEASES.

(a) GAO STUDY.—The Comptroller General of the United States shall conduct a study that reviews a geographically diverse sample of States and territories that, in response to the COVID–19 pandemic, implemented preparedness and response plans that included isolation and quarantine recommendations or requirements. Such study shall include—

(1) a review of such State and territorial preparedness and response plans in place during the

COVID–19 pandemic, an assessment of the extent to which such plans facilitated or presented challenges to State and territorial responses to such public health emergency, including response activities relating to isolation and quarantine to prevent the spread of COVID–19; and

(2) a description of the technical assistance provided by the Federal Government to help States and territories facilitate such response activities during responses to relevant public health emergencies declared by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, including the public health emergency with respect to COVID–19, and a review of the degree to which such State and territorial plans were implemented and subsequently revised in response to the COVID–19 pandemic to address any challenges.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit a report on the study under subsection (a) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

TITLE II—IMPROVING PUBLIC HEALTH PREPAREDNESS AND RESPONSE CAPACITY

Subtitle A—Addressing Disparities and Improving Public Health Emergency Responses

SEC. 201. ADDRESSING SOCIAL DETERMINANTS OF HEALTH AND IMPROVING HEALTH OUTCOMES.

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

(1) by inserting after section 317U the following:

"SEC. 317V. ADDRESSING SOCIAL DETERMINANTS OF HEALTH AND IMPROVING HEALTH OUTCOMES.

''(a) IN GENERAL.—The Secretary shall, as appropriate, award grants, contracts, or cooperative agreements to eligible entities for the conduct of evidence-based or evidence-informed projects, which may include the development of networks to improve health outcomes and reduce health disparities by improving the capacity of such entities to address social determinants of health in communities.

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

''(1)(A) be a State, local, or Tribal health department, community-based organization, Indian Tribe or Tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), or other public or private entity, as the Secretary determines appropriate; or

''(B) be a consortia or public-private partnership of entities described in subparagraph (A);

''(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary shall require;

''(3) in the case of an entity other than a community-based organization, demonstrate a history of successfully working with an established community-based organization to address health disparities;

''(4) submit a plan to conduct activities described in subsection (a) based on a community needs assessment that takes into account community input; and

''(5) demonstrate the capacity to effectively implement evidence-based or evidence-informed strategies to address health disparities among underserved

populations, which may include rural, racial, and ethnic minority populations and people with disabilities, in a timely manner.

''(c) USE OF FUNDS.—An entity described in subsection (b) shall use funds received under subsection (a), in consultation with State, local, and Tribal health departments, community-based organizations, and other entities with experience addressing social determinants of health or reducing health disparities, as applicable, for one or more of the following purposes:

''(1) Supporting the implementation, evaluation, and dissemination of strategies, including culturally-appropriate strategies, to address social determinants of health, based on the identified needs of the community that is the subject of the assessment submitted under subsection (b)(4), through evidence-informed or evidence-based programs and through the support and use of public health and health care professionals to address such social determinants of health.

''(2) Establishing, maintaining, or improving, in consultation with State, local, or Tribal health departments, technology platforms or networks to support coordination among appropriate entities, and providing information on health and related social

services, which may include activities to improve data collection for public health purposes, in a manner that is consistent with applicable Federal and State privacy law.

''(3) Implementing best practices for improving health outcomes and reducing disease among underserved populations, including rural or racial and ethnic minority populations.

''(4) Supporting consideration of social determinants of health in preparing for, and responding to, public health emergencies, through outreach, education, research, and other relevant activities.

''(d) BEST PRACTICES AND TECHNICAL ASSISTANCE.—The Secretary, in consultation with the Director of the Office of Minority Health, may award grants, contracts, and cooperative agreements to public or nonprofit private entities, including minority serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 326(e)(1) of the Higher Education Act of 1965 and institutions described in section 371(a) of such Act of 1965), to—

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

''(2) provide technical assistance, training, and evaluation assistance to award recipients under subsection (a);

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

''(4) establish or operate regional centers to develop, evaluate, and disseminate effective strategies on the utilization of preventive health care services to address social determinants of health, including supporting research and training related to such strategies.

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

''(f) REPORT.—Not later than September 30, 2026, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes information on activities funded under this section. Such report shall include a description of—

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

networks developed or utilized to coordinate health and related social services and any changes in workforce capacity or capabilities;

''(2) improvements in health outcomes and in reducing health disparities in medically underserved communities;

''(3) activities conducted to support consideration of social determinants of health in preparing for, and responding to, public health emergencies, through outreach, education, and other relevant activities;

''(4) communities and populations served by recipients of awards under subsection (a);

''(5) activities supported under subsection (e); and

''(6) other relevant activities and outcomes, as determined by the Secretary.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $70,000,000 for each of fiscal years 2023 through 2027.''; and

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

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

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

SEC. 202. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE REPORT.

(a) IN GENERAL.—Not later than 45 days after the date of enactment of this Act, the Secretary of Health and Human Services shall seek to enter into a contract with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the ''National Academies'') to conduct a study to examine health disparities and the effect of such disparities on health outcomes, which may include health outcomes related to pandemic and other public health emergencies.

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

report informed by the study conducted under such subsection that includes—

(1) consideration of previous recommendations made by the National Academies related to health disparities, including in the report titled ''Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare'';

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

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

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

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

Subtitle B—Improving Public Health Data

SEC. 211. MODERNIZING BIOSURVEILLANCE CAPABILITIES AND INFECTIOUS DISEASE DATA COLLECTION.

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

(1) in subsection (b)(1)(A), by striking ‘‘, and local’’ and inserting ‘‘, local, and Tribal’’;

(2) in subsection (c)—

(A) in paragraph (1), by inserting ‘‘modernize,’’ after ‘‘establish,’’;

(B) in paragraph (3)(B), by inserting ‘‘, and make recommendations to improve the quality of data collected pursuant to subparagraph (A) to ensure complete, accurate, and timely sharing of such data, as appropriate, across such elements as described in subparagraph (A)’’ after ‘‘under subparagraph (A)’’;

(C) in paragraph (5)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i), by striking ‘‘and operating’’ and inserting ‘‘, operating, and updating, as appropriate,’’;

(II) in clause (iv), by striking ''and'' at the end;

(III) in clause (v), by striking the period and inserting ''; and''; and

(IV) by adding at the end the following:

''(vi) in collaboration with State, local, and Tribal public health officials, integrate and update applicable existing public health data systems and networks of the Department of Health and Human Services to reflect technological advancements, consistent with section 2823, as applicable.''; and

(ii) in subparagraph (B)—

(I) in clause (i), by inserting ''and 180 days after the date of enactment of the PREVENT Pandemics Act,'' after ''Innovation Act of 2019,'';

(II) in clause (ii), by inserting ''experts in privacy and data security;'' after ''forecasting);''; and

(III) in clause (iii)—

(aa) in subclause (V), by striking ''and'' at the end;

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

(cc) by adding at the end the following:

''(VII) strategies to integrate laboratory and public health data systems and capabilities to support rapid and accurate reporting of laboratory test results and associated relevant data;

''(VIII) strategies to improve the collection and reporting of relevant, aggregated, deidentified demographic data to inform responses to public health emergencies, including identification of at-risk populations and to address potential health disparities; and

''(IX) strategies to improve the electronic exchange of health information between State and local health departments and health care providers

and facilities to improve public health surveillance.''; and

(D) in paragraph (6)(A)—

(i) in the matter preceding clause (i), by inserting ''and every 5 years thereafter,'' after ''Innovation Act of 2019,''

(ii) in clause (iii)—

(I) in subclause (III), by striking ''and'' at the end; and

(II) by adding at the end the following:

''(V) improve coordination and collaboration, as appropriate, with other Federal departments; and

''(VI) implement applicable lessons learned from recent public health emergencies to address gaps in situational awareness and biosurveillance capabilities;'';

(iii) in clause (iv), by striking ''and'' at the end;

(iv) in clause (v), by striking the period and inserting '', including a description of how such steps will further the

goals of the network, consistent with paragraph (1); and''; and

(v) by adding at the end the following:

''(vi) identifies and demonstrates measurable steps the Secretary will take to further develop and integrate infectious disease detection, support rapid and accurate reporting of laboratory test results during a public health emergency, and improve coordination and collaboration with State, local, and Tribal public health officials, clinical laboratories, and other entities with expertise in public health surveillance.'';

(3) in subsection (d)—

(A) in paragraph (1), by inserting '', acting through the Director of the Centers for Disease Control and Prevention and in coordination with the heads of other appropriate agencies and offices within the Department of Health and Human Services,'' after ''the Secretary'';

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

other partnerships entered into to improve such capacity'' before the semicolon; and

(C) by adding at the end the following:

''(6) NON-DUPLICATION OF EFFORT.—The Secretary shall ensure that activities carried out under an award under this subsection do not unnecessarily duplicate efforts of other agencies and offices within the Department of Health and Human Services.'';

(4) by amending subsection (i) to read as follows:

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

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

''(2) to carry out subsections (b), (c), and (d), $136,800,000 for each of fiscal years 2022 and 2023.''; and

(5) by striking ''tribal'' each place it appears and inserting ''Tribal''.

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

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

other Federal departments or agencies, as appropriate, shall issue guidance to support collaboration relating to genomic sequencing of pathogens, including the use of new and innovative approaches and technology for the detection, characterization, and sequencing of pathogens, to improve public health surveillance and preparedness and response activities, consistent with section 2824 of the Public Health Service Act, as added by subsection (b). Such guidance shall address the secure sharing, for public health surveillance purposes, of specimens of such pathogens, between appropriate entities and public health authorities, consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), as applicable, and in a manner that protects personal privacy to the extent required by applicable privacy law, at a minimum, and the appropriate use of sequence data derived from such specimens.

(b) GENOMIC SEQUENCING PROGRAM.—Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.) is amended by adding at the end the following

"SEC. 2824. GENOMIC SEQUENCING, ANALYTICS, AND PUBLIC HEALTH SURVEILLANCE OF PATHOGENS PROGRAM.

''(a) GENOMIC SEQUENCING, ANALYTICS, AND PUBLIC HEALTH SURVEILLANCE OF PATHOGENS PROGRAM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health and heads of other departments and agencies, as appropriate, shall strengthen and expand activities related to genomic sequencing of pathogens, including new and innovative approaches and technology for the detection, characterization, and sequencing of pathogens, analytics, and public health surveillance, including—

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

''(A) identify and respond to emerging infectious disease threats; and

''(B) identify the potential use of genomic sequencing technologies, advanced computing, and other advanced technology to inform surveillance activities and incorporate the use of such technologies, as appropriate, into related activities;

''(2) providing technical assistance and guidance to State, Tribal, local, and territorial public health departments to increase the capacity of such departments to perform genomic sequencing of pathogens, including recipients of funding under section 2821;

''(3) carrying out activities to enhance the capabilities of the public health workforce with respect to pathogen genomics, epidemiology, and bioinformatics, including through training; and

''(4) continuing and expanding activities, as applicable, with public and private entities, including relevant departments and agencies, laboratories, academic institutions, and industry.

''(b) PARTNERSHIPS.—For the purposes of carrying out the activities described in subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants, contracts, or cooperative agreements to entities, including academic and other laboratories, with expertise in genomic sequencing for public health purposes, including new and innovative approaches to, and related technology for, the detection, characterization, and sequencing of pathogens.

''(c) CENTERS OF EXCELLENCE.—

''(1) IN GENERAL.—The Secretary shall, as appropriate, award grants, contracts, or cooperative agreements to public health agencies for the establishment or operation of centers of excellence to promote innovation in pathogen genomics and molecular epidemiology to improve the control of and response to pathogens that may cause a public health emergency. Such centers shall, as appropriate—

''(A) identify and evaluate the use of genomics, or other related technologies that may advance public health preparedness and response;

''(B) improve the identification, development, and use of tools for integrating and analyzing genomic and epidemiologic data;

''(C) assist with genomic surveillance of, and response to, infectious diseases, including analysis of pathogen genomic data;

''(D) conduct applied research to improve public health surveillance of, and response to, infectious diseases through innovation in pathogen genomics and molecular epidemiology; and

''(E) develop and provide training materials for experts in the fields of genomics,

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

''(2) REQUIREMENTS.—To be eligible for an award under paragraph (1), an entity shall submit to the Secretary an application containing such information as the Secretary may require, including a description of how the entity will partner, as applicable, with academic institutions or a consortium of academic partners that have relevant expertise, such as microbial genomics, molecular epidemiology, or the application of bioinformatics or statistics.

''(d) AUTHORIZATION.—For purposes of carrying out this section, there are authorized to be appropriated $175,000,000 for each of fiscal years 2023 through 2027.''.

SEC. 213. SUPPORTING PUBLIC HEALTH DATA AVAILABILITY AND ACCESS.

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

(1) by striking ''In carrying out'' and inserting the following:

''(A) IN GENERAL.—In carrying out''; and

(2) by striking ''shall, as appropriate and'' and inserting ''shall, not later than 2 years after the date

of enactment of the PREVENT Pandemics Act,''; and

(3) by adding at the end the following:

''(B) SELECTION OF DATA AND TECHNOLOGY STANDARDS.—The standards designated as described in subparagraph (A) may include standards to improve—

''(i) the exchange of electronic health information for—

''(I) electronic case reporting;

''(II) syndromic surveillance;

''(III) reporting of vital statistics; and

''(IV) reporting test orders and results electronically, including from laboratories;

''(ii) automated electronic reporting to relevant public health data systems of the Centers for Disease Control and Prevention; and

''(iii) such other use cases as the Secretary determines appropriate.

''(C) NO DUPLICATIVE EFFORTS.—

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

Secretary, in consultation with the Office of the National Coordinator for Health Information Technology, may use input gathered (including input and recommendations gathered from the Health Information Technology Advisory Committee), and materials developed, prior to the date of enactment of the PREVENT Pandemics Act.

''(ii) PREVIOUSLY ADOPTED STANDARDS.—The data and technology standards designated pursuant to this paragraph may include the adoption of standards previously adopted by the Secretary pursuant to section 3004.

''(D) PRIVACY AND SECURITY.—Nothing in this paragraph shall be construed as modifying applicable Federal or State information privacy or security law.''.

(b) STUDY ON LABORATORY INFORMATION STANDARDS.—

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

standards for electronic ordering and reporting of laboratory test results.

(2) AREAS OF CONCENTRATION.—In conducting the study under paragraph (1), the Office of the National Coordinator for Health Information Technology shall—

(A) determine the extent to which clinical laboratories are using standards for electronic ordering and reporting of laboratory test results;

(B) assess trends in laboratory compliance with standards for ordering and reporting laboratory test results and the effect of such trends on the interoperability of laboratory data with public health data systems;

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

(D) identify any challenges associated with using or complying with standards and reporting laboratory test results with data elements identified in standards for electronic ordering and reporting of such results; and

(E) review other relevant areas determined appropriate by the Office of the National Coordinator for Health Information Technology.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Office of the National Coordinator for Health Information Technology shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the findings of the study conducted under paragraph (1).

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

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

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, as appropriate, facilitate the development of, or updates to, memoranda of understanding, data use agreements, or other applicable interagency agreements regarding appropriate access, exchange, and use of public health data between

the Centers for Disease Control and Prevention, the Office of the Assistant Secretary for Preparedness and Response, other relevant agencies or offices within the Department of Health and Human Services, and other relevant Federal agencies, in order to prepare for, identify, monitor, and respond to declared or potential public health emergencies.

(B) REQUIREMENTS.—In carrying out activities pursuant to subparagraph (A), the Secretary shall—

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

(I) address the methods of granting access to data held by one agency or office with another to support the respective missions of such agencies or offices;

(II) consider minimum necessary principles of data sharing for appropriate use;

(III) include appropriate privacy and cybersecurity protections; and

(IV) are subject to regular updates, as appropriate;

(ii) collaborate with the Centers for Disease Control and Prevention, the Office of the Assistant Secretary for Preparedness and Response, the Office of the Chief Information Officer, and, as appropriate, the Office of the National Coordinator for Health Information Technology, and other entities within the Department of Health and Human Services; and

(iii) consider the terms and conditions of any existing data use agreements with other public or private entities and any need for updates to such existing agreements, consistent with paragraph (2).

(2) DATA USE AGREEMENTS WITH EXTERNAL ENTITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Assistant Secretary for Preparedness and Response, may update memoranda of understanding, data use agreements, or other applicable agreements and contracts to improve appropriate access, exchange, and use of public health data between the Centers for Disease Control and Preven-

tion and the Office of the Assistant Secretary for Preparedness and Response and external entities, including State, Tribal, and territorial health departments, laboratories, hospitals and other health care providers, electronic health records vendors, and other entities, as applicable and appropriate, in order to prepare for, identify, monitor, and respond to declared or potential public health emergencies.

(3) REPORT.—Not later than 90 days after the date of enactment of this Act, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the status of the agreements under this subsection.

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

"SEC. 310B. IMPROVING INFORMATION SHARING AND AVAILABILITY OF PUBLIC HEALTH DATA.

"(a) IN GENERAL.—The Secretary may, in consultation with State, local, and Tribal public health officials, carry out activities to improve the availability of appropriate and applicable public health data related to commu-

nicable diseases, and information sharing between, the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, and such State, local, and Tribal public health officials, which may include such data from—

''(1) health care providers and facilities;

''(2) public health and clinical laboratories; and

''(3) State, local, and Tribal health departments.

''(b) CONTENT, FORM, AND MANNER.—The Secretary shall, consistent with the requirements of this section, work with such officials and relevant stakeholders to provide information on the content, form, and manner in which such data may most effectively support the ability of State, local, and Tribal health departments to respond to such communicable diseases, including related to the collection and reporting of demographic and other relevant data elements.

''(c) DECREASED BURDEN.—In facilitating the coordination of efforts under subsection (a), the Secretary shall make reasonable efforts to limit reported public health data to the minimum necessary information needed to accomplish the intended public health surveillance purpose.

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

''(1) an individual is identified through such data; or

''(2) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources or the application of technology could be used to deduce the identity of an individual.''.

(e) IMPROVING PUBLIC HEALTH DATA COLLECTION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall award grants, contracts, or cooperative agreements to eligible entities for purposes of identifying, developing, or disseminating best practices in the collection of electronic health information and the use of designated data standards and implementation specifications to improve the quality and completeness of data, including de-

mographic data, collected, accessed, or used for public health purposes and to address health disparities and related health outcomes.

(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection an entity shall—

(A) be a health care provider, academic medical center, community-based organization, State, local governmental entity, Indian Tribe or Tribal organization (as such terms are defined in section 4 of the Indian Self Determination and Education Assistance Act (25 U.S.C. 5304)), urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)), or other appropriate public or private nonprofit entity, or a consortia of any such entities; and

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

(3) ACTIVITIES.—Entities receiving awards under this subsection shall use such award to develop and test best practices for training health care providers to use standards and implementation specifications that assist in the capture, access, ex-

change, and use of electronic health information, including demographic information, disability status, veteran status, housing status, functional status, and other data elements. Such activities shall include, at a minimum—

(A) improving, understanding, and using data standards and implementation specifications;

(B) developing or identifying methods to improve communication with patients in a culturally- and linguistically-appropriate manner, including to better capture information related to demographics of such individuals;

(C) developing methods for accurately categorizing and recording patient responses using available data standards;

(D) educating providers regarding the utility of such information for public health purposes and the importance of accurate collection and recording of such data; and

(E) other activities, as the Secretary determines appropriate.

(4) REPORTING.—

(A) REPORTING BY AWARD RECIPIENTS.—Each recipient of an award under this sub-

section shall submit to the Secretary a report on the results of best practices identified, developed, or disseminated through such award.

(B) REPORT TO CONGRESS.—Not later than 1 year after the completion of the program under this subsection, the Secretary shall submit a report to Congress on the success of best practices developed under such program, opportunities for further dissemination of such best practices, and recommendations for improving the capture, access, exchange, and use of information to improve public health and reduce health disparities.

(5) NON-DUPLICATION OF EFFORTS.—The Secretary shall ensure that the activities and programs carried out under this subsection are free of unnecessary duplication of effort.

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

SEC. 214. EPIDEMIC FORECASTING AND OUTBREAK ANALYTICS.

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

"SEC. 2825. EPIDEMIC FORECASTING AND OUTBREAK ANALYTICS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall continue activities related to the development of infectious disease outbreak analysis capabilities to enhance the prediction, modeling, and forecasting of potential public health emergencies and other infectious disease outbreaks, which may include activities to support preparedness for, and response to, such emergencies and outbreaks. In carrying out this subsection, the Secretary shall identify strategies to include and leverage, as appropriate, the capabilities to public and private entities, which may include conducting such activities through collaborative partnerships with public and private entities, including academic institutions, and other Federal agencies, consistent with section 319D, as applicable.

''(b) CONSIDERATIONS.—In carrying out subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may consider public health data and, as appropriate, other data sources

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

''(c) ANNUAL REPORTS.—Not later than 1 year after the date of enactment of this section, and annually thereafter for each of the subsequent 4 years, the Secretary shall prepare and submit a report, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, regarding an update on progress on activities conducted under this section to develop infectious disease outbreak analysis capabilities and any additional information relevant to such efforts.''.

SEC. 215. REPORT ON CDC DATA PORTAL.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding public health data modernization initiatives, surveillance investments, and public health data reporting modernization initiatives under this Act (including the amendments made by this Act) and the Public Health Service Act (42 U.S.C.

201 et seq.), and provide recommendations on the feasibility of the use of a web-based information technology platform (referred to in this section as the ''platform'') for the streamlining of existing voluntary submissions of public health data for all State, local, Tribal, and territorial entities that report such data to the Centers for Disease Control and Prevention, and whether such platform would reduce the reporting burden for such entities.

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

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

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

(3) leverage private sector technologies; and

(4) provide for the streamlining of data reporting to the greatest extent possible.

SEC. 216. PUBLIC HEALTH DATA TRANSPARENCY.

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

trol and Prevention with respect to the collection and dissemination of public health data related to a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d) or a potential public health emergency.

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

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

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

(3) considerations regarding the requirements and limitations of data use agreements for such purposes, as applicable.

Subtitle C—Revitalizing the Public Health Workforce

SEC. 221. IMPROVING RECRUITMENT AND RETENTION OF THE FRONTLINE PUBLIC HEALTH WORKFORCE.

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

(1) in subsection (a)—

(A) by striking ''supply of'' and inserting ''supply of, and encourage recruitment and retention of,''; and

(B) by striking ''Federal,'';

(2) in subsection (b)—

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

''(1)(A)(i) be accepted for enrollment, or be enrolled, as a student in an accredited institution of higher education or school of public health in the final semester (or equivalent) of a program leading to a certificate or degree, including a master's or doctoral degree, in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or another subject matter related to public health; and

''(ii) be employed by, or have accepted employment with, a State, local, or Tribal public health agency, or a related training fellowship at such State, local, or Tribal public health agency, as recognized by the Secretary, to commence upon graduation; or''; and

(B) in paragraph (1)(B)—

(i) in clause (i)—

(I) by striking ''accredited educational institution in a State or territory'' and inserting ''accredited institution of higher education or school of public health''; and

(II) by striking ''a public health or health professions degree or certificate'' and inserting ''a certificate or degree, including a master's or doctoral degree, in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or another subject matter related to public health''; and

(ii) in clause (ii)—

(I) by striking ''Federal,''; and

(II) by striking ''fellowship,'' and inserting ''fellowship at such State, local, or Tribal public health agency,'';

(3) in subsection (c)(2)—

(A) by striking ''Federal,''; and

(B) by striking ''equal to the greater of—'' and all that follows through the end of subparagraph (B) and inserting ''of at least 3 consecutive years;'';

(4) in subsection (d)—

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

''(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), for the individual toward the outstanding principal and interest on education loans incurred by the individual in the pursuit of the relevant degree or certificate described in subsection (b)(1) in accordance with the terms of the contract.''; and

(B) in paragraph (2)—

(i) by striking ''For each year'' and inserting the following:

''(A) IN GENERAL.—For each year'';

(ii) by striking ''$35,000'' and inserting ''$50,000'';

(iii) by striking ''$105,000'' and inserting ''$150,000''; and

(iv) by adding at the end the following:

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

''(i) an appropriate proportion of contracts are awarded to individuals who are eligible to participate in the program pursuant to subsection (b)(1)(A); and

''(ii) contracts awarded under this section are equitably distributed among—

''(I) the geographical regions of the United States;

''(II) local, State, and Tribal public health departments; and

''(III) such public health departments under subclause (II) serving rural and urban areas.'';

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

other related school'' and inserting ''with a contract to serve under subsection (c)'';

(6) in subsection (f), by adding at the end the following: ''In the event that a participant fails to either begin or complete the obligated service requirement of the loan repayment contract under this section, the Secretary may waive or suspend either the unfulfilled service or the assessed damages as provided for under section 338E(d), as appropriate.'';

(7) by redesignating subsection (g) as subsection (h);

(8) by inserting after subsection (f) the following:

''(g) ELIGIBLE LOANS.—The loans eligible for repayment under this section are each of the following:

''(1) Any loan for education or training for employment by a health department.

''(2) Any loan under part E of title VIII (relating to nursing student loans).

''(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, Federal Direct Unsubsidized Stafford Loan, or Federal Direct Consolidation Loan (as such terms are used in section 455 of the Higher Education Act of 1965).

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

''(5) Any other Federal loan, as the Secretary determines appropriate.'';

(9) in subsection (h), as so redesignated, by striking ''$195,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015'' and inserting ''such sums as may be necessary for each of fiscal years 2022 through 2025''; and

(10) by striking ''tribal'' each place such term appears and inserting ''Tribal''.

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

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

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

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

(C) Federal efforts to improve hiring, recruitment, and retention of the public health workforce; and

(2) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review.

SEC. 222. AWARDS TO SUPPORT COMMUNITY HEALTH WORKERS AND COMMUNITY HEALTH.

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

(1) by amending the section heading to read as follows: ''**AWARDS TO SUPPORT COMMUNITY HEALTH WORKERS AND COMMUNITY HEALTH**'';

(2) by amending subsection (a) to read as follows:

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with the Administrator of the Health Resources and Services Administration, shall award grants, contracts, or cooperative agreements to eli-

gible entities to promote positive health behaviors and outcomes for populations in medically underserved communities by leveraging community health workers, including by addressing ongoing and longer-term community health needs, and by building the capacity of the community health worker workforce. Such grants, contracts, and cooperative agreements shall be awarded in alignment and coordination with existing funding arrangements supporting community health workers.'';

(3) in subsection (b)—

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

(i) by striking ''Grants awarded'' and inserting ''Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded''; and

(ii) by striking ''support community health workers'';

(B) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively;

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

''(1) recruit, hire, train, and retain community health workers that reflect the needs of the community;

''(2) support community health workers in providing education and outreach, in a community setting, regarding—

''(A) health conditions prevalent in—

''(i) medically underserved communities (as defined in section 799B), particularly racial and ethnic minority populations; and

''(ii) other such at-risk populations or geographic areas that may require additional support during public health emergencies, which may include counties identified by the Secretary using applicable measures developed by the Centers for Disease Control and Prevention or other Federal agencies; and

''(B) addressing social determinants of health and eliminating health disparities, including by—

''(i) promoting awareness of services and resources to increase access to health care, mental health and substance use disorder services, child services, technology, housing services, educational services, nutrition services, employment services, and other services; and

''(ii) assisting in conducting individual and community needs assessments;

''(3) educate community members, including regarding effective strategies to promote healthy behaviors;'';

(D) in paragraph (4), as so redesignated, by striking ''to educate'' and inserting ''educate'';

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

(i) by striking ''to identify'' and inserting ''identify'';

(ii) by striking ''healthcare agencies'' and inserting ''health care agencies''; and

(iii) by striking ''healthcare services and to eliminate duplicative care; or'' and inserting ''health care services and to streamline care, including serving as a liai-

son between communities and health care agencies; and''; and

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

(i) by striking ''to educate, guide, and provide'' and inserting ''support community health workers in educating, guiding, or providing''; and

(ii) by striking ''maternal health and prenatal care'' and inserting ''chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes'';

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

(5) in subsection (d)—

(A) in the matter preceding paragraph (1), by striking ''awarding grants'' and inserting ''making awards'';

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

''(1) propose to serve—

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

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

''(C) populations residing in health professional shortage areas (as defined in section 332(a));

''(D) populations residing in maternity care health professional target areas identified under section 332(k); or

''(E) rural or traditionally underserved populations, including racial and ethnic minority populations or low-income populations;'';

(C) in paragraph (2), by striking ''; and'' and inserting '', including rural populations and racial and ethnic minority populations;'';

(D) in paragraph (3), by striking ''with community health workers.'' and inserting ''and established relationships with community health workers in the communities expected to be served by the program;'' and

(E) by adding at the end the following:

''(4) develop a plan for providing services to the extent practicable, in the language and cultural context most appropriate to individuals expected to be served by the program; and

''(5) propose to use evidence-informed or evidence-based practices, as applicable and appropriate.'';

(6) in subsection (e)—

(A) by striking ''community health worker programs'' and inserting ''eligible entities''; and

(B) by striking ''and one-stop delivery systems under section 121(e)'' and inserting '', health professions schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 326(e)(1) of the Higher Education Act of 1965 and institutions described in section 371(a) of such Act), area health education centers under section 751 of this Act, and one-stop delivery systems under section 121'';

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

''(f) TECHNICAL ASSISTANCE.—The Secretary may provide to eligible entities that receive awards under subsection (a) technical assistance with respect to planning,

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

''(g) DISSEMINATION OF BEST PRACTICES.—Not later than 4 years after the date of enactment of the PREVENT Pandemics Act, the Secretary shall, based on activities carried out under this section and in consultation with relevant stakeholders, identify and disseminate evidence-based or evidence-informed practices regarding recruitment and retention of community health workers and paraprofessionals to address ongoing public health and community health needs, and to prepare for, and respond to, future public health emergencies.

''(h) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the PREVENT Pandemics Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the effectiveness of the program under this section in addressing ongoing public health and community health needs. Such report shall include recommendations regarding any improvements to such program, including recommendations for how to improve recruitment, training, and retention of the community health workforce.

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

(8) by redesignating subsection (k) as subsection (j); and

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

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

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

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

(i) by striking ''entity (including a State or public subdivision of a State'' and inserting ''entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization''; and

(ii) by striking ''as defined in section 1861(aa) of the Social Security Act))'' and inserting ''(as defined in section 1861(aa)(4) of the Social Security Act)''; and

(D) by adding at the end the following:

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

''(3) URBAN INDIAN ORGANIZATION.—The term 'urban Indian organization' has the meaning given such term in section 4 of the Indian Health Care Improvement Act.''.

(b) GAO STUDY AND REPORT.—Not later than 1 year after the date of submission of the report under subsection (h) of section 399V of the Public Health Service Act (42 U.S.C. 280g–11), as amended by subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the program authorized under such section 399V, including a review of the efforts of the Secretary of Health and Human Services to coordinate such program with applicable programs of the Health Resources and Services Administration to ensure there is no unnecessary duplication of efforts among such programs, and identification of any areas of duplication.

SEC. 223. IMPROVING PUBLIC HEALTH EMERGENCY RESPONSE CAPACITY.

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

''(g) CERTAIN APPOINTMENTS TO SUPPORT PUBLIC HEALTH EMERGENCY RESPONSES.—

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

''(A) address a critical hiring need directly related to responding to a public health emergency declared by the Secretary under this section; or

''(B) address a severe shortage of candidates that impacts the operational capacity of the Department of Health and Human Services to respond in the event of a public health emer-

gency declared by the Secretary under this section.

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

''(A) 400 individuals under paragraph (1)(A); and

''(B) 100 individuals under paragraph (1)(B).

''(3) COMPENSATION.—The annual rate of basic pay of an individual appointed under this subsection shall be determined in accordance with chapter 51 and subchapter III of chapter 53 of title 5, United States Code.

''(4) REPORTING.—The Secretary shall establish and maintain records regarding the use of the authority under this subsection, including—

''(A) the number of positions filled through such authority;

''(B) the types of appointments of such positions;

''(C) the titles, occupational series, and grades of such positions;

"(D) the number of positions publicly noticed to be filled under such authority;

"(E) the number of qualified applicants who apply for such positions;

"(F) the qualification criteria for such positions; and

"(G) the demographic information of individuals appointed to such positions.

"(5) NOTIFICATION TO CONGRESS.—In the event the Secretary, within a single fiscal year, directly appoints more than 50 percent of the individuals allowable under either subparagraph (A) or (B) of paragraph (2), the Secretary shall, not later than 15 days after the date of such action, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such notification shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include—

"(A) information on each such appointment within such fiscal year;

"(B) a description of how each such position relates to the requirements of subparagraph (A) or (B) of paragraph (1); and

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

"(6) REPORTS TO CONGRESS.—Not later than September 30, 2023, and annually thereafter for each fiscal year in which the authority under this subsection is used, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under this subsection within the fiscal year and a description of how the positions relate to the requirements of subparagraph (A) or (B) of paragraph (1).

"(7) SUNSET.—The authority under this subsection shall expire on September 30, 2028.".

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

section 319 of the Public Health Service Act (42 U.S.C. 247d), as added by subsection (a), and again 180 days after the date on which the authority provided under section 319(g) of such Act expires pursuant to paragraph (7) of such section, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of the authority provided under such section. Such report shall, in a manner that protects personal privacy, at a minimum, include information on—

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

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

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

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

(5) sources used to identify candidates for filling such positions;

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

(7) aggregated demographic information related to individuals appointed under each such subparagraph; and

(8) any challenges, limitations, or gaps related to the use of the authority under each such subparagraph and any related recommendations to address such challenges, limitations, or gaps.

SEC. 224. EXTENSION OF AUTHORITIES TO SUPPORT HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

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

SEC. 225. INCREASING EDUCATIONAL OPPORTUNITIES FOR ALLIED HEALTH PROFESSIONS.

Section 755(b) of the Public Health Service Act (42 U.S.C. 294e(b)) is amended by adding at the end the following:

''(4) Increasing educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology, and speech-language pathology professions, which may include offering scholarships or stipends and carrying out other activities to improve retention, for individuals from disadvantaged

backgrounds or individuals who are underrepresented in such professions.''.

SEC. 226. PUBLIC HEALTH SERVICE CORPS ANNUAL AND SICK LEAVE.

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

(1) in subsection (a)—

(A) by striking ''Reserve Corps'' and inserting ''Ready Reserve Corps''; and

(B) by striking '': *Provided*, That such regulations shall not authorize annual leave to be accumulated in excess of sixty days'';

(2) by inserting after subsection (a) the following:

''(b) The regulations described in subsection (a) may authorize accumulated annual leave of not more than 120 days for any commissioned officer of the Regular Corps or officer of the Ready Reserve Corps on active duty.''; and

(3) by redesignating subsection (d) as subsection (c).

(b) APPLICATION.—The amendments made by subsection (a) shall apply with respect to accumulated annual leave (as defined in section 219 of the Public Health Service Act (42 U.S.C. 210–1)) that a commissioned officer

of the Regular Corps or officer of the Ready Reserve Corps on active duty would, but for the regulations described in such section, lose at the end of fiscal year 2022 or a subsequent fiscal year.

Subtitle D—Improving Public Health Responses

SEC. 231. CENTERS FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE.

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

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

''(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants, contracts, or cooperative agreements to institutions of higher education, including accredited schools of public health, or other nonprofit private entities to establish or maintain a network of Centers for Public Health Preparedness and Response (referred to in this subsection as 'Centers').

''(2) ELIGIBILITY.—To be eligible to receive an award under this subsection, an entity shall submit

to the Secretary an application containing such information as the Secretary may require, including a description of how the entity will—

''(A) coordinate relevant activities with applicable State, local, and Tribal health departments and officials, health care facilities, and health care coalitions to improve public health preparedness and response, as informed by the public health preparedness and response needs of the community, or communities, involved;

''(B) prioritize efforts to implement evidence-informed or evidence-based practices to improve public health preparedness and response, including by helping to reduce the transmission of emerging infectious diseases; and

''(C) use funds awarded under this subsection, including by carrying out any activities described in paragraph (3).

''(3) USE OF FUNDS.—The Centers established or maintained under this subsection shall use funds awarded under this subsection to carry out activities to advance public health preparedness and response capabilities, which may include—

"(A) identifying, translating, and disseminating promising research findings or strategies into evidence-informed or evidence-based practices to inform preparedness for, and responses to, chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and other public health emergencies, which may include conducting research related to public health preparedness and response systems;

"(B) improving awareness of such evidence-informed or evidence-based practices and other relevant scientific or public health information among health care professionals, public health professionals, other stakeholders, and the public, including through the development, evaluation, and dissemination of trainings and training materials, consistent with section 2802(b)(2), as applicable and appropriate, and with consideration given to existing training materials, to support preparedness for, and responses to, such threats;

"(C) utilizing and expanding relevant technological and analytical capabilities to inform public health and medical preparedness and response efforts;

''(D) expanding activities, including through public-private partnerships, related to public health preparedness and response, including participation in drills and exercises and training public health experts, as appropriate; and

''(E) providing technical assistance and expertise that relies on evidence-based practices, as applicable, related to responses to public health emergencies, as appropriate, to State, local, and Tribal health departments and other entities pursuant to paragraph (2)(A).

''(4) DISTRIBUTION OF AWARDS.—In awarding grants, contracts, or cooperative agreements under this subsection, the Secretary shall support not fewer than 10 Centers, subject to the availability of appropriations, and ensure that such awards are equitably distributed among the geographical regions of the United States.''; and

(2) in subsection (f)(1)(C), by striking '', of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection''.

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

SEC. 232. VACCINE DISTRIBUTION PLANS.

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

(1) in subsection (a)—

(A) by inserting ‘‘, or other federally purchased vaccine to address another pandemic’’ before the period at the end of the first sentence; and

(B) by inserting ‘‘or other pandemic’’ before the period at the end of the second sentence; and

(2) in subsection (d), by inserting ‘‘or other pandemics’’ after ‘‘influenza pandemics’’.

SEC. 233. COORDINATION AND COLLABORATION REGARDING BLOOD SUPPLY.

(a) IN GENERAL.—The Secretary of Health and Human Services, or the Secretary's designee, shall—

(1) ensure coordination and collaboration between relevant Federal departments and agencies related to the safety and availability of the blood supply, including—

(A) the Department of Health and Human Services, including the Office of the Assistant Secretary for Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Office of the Assistant Sec-

retary for Preparedness and Response, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration;

(B) the Department of Defense; and

(C) the Department of Veterans Affairs; and

(2) consult and communicate with private stakeholders, including blood collection establishments, health care providers, accreditation organizations, researchers, and patients, regarding issues related to the safety and availability of the blood supply.

(b) STREAMLINING BLOOD DONOR INPUT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary and that is initiated by the Secretary of Health and Human Services to solicit information from blood donors or potential blood donors to support the development of recommendations by the Secretary concerning blood donation.

TITLE III—ACCELERATING RESEARCH AND COUNTERMEASURE DISCOVERY

Subtitle A—Fostering Research and Development and Improving Coordination

SEC. 301. RESEARCH AND ACTIVITIES RELATED TO LONG-TERM HEALTH EFFECTS OF SARS–COV–2 INFECTION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, as appropriate—

(1) continue to conduct or support basic, clinical, epidemiological, behavioral, and translational research and public health surveillance related to the pathogenesis, prevention, diagnosis, and treatment of the long-term health effects of SARS–CoV–2 infection; and

(2) in consultation with health professional associations, researchers, and other relevant experts, develop and inform recommendations, guidance, and provide educational materials for health care providers and the general public on the long-term effects of SARS–CoV–2 infection, consistent with the

findings of studies and research under paragraph (1).

(b) CONSIDERATIONS.—In conducting or supporting research under this section, the Secretary shall consider the diversity of research participants or cohorts to ensure inclusion of a broad range of participants, as applicable and appropriate.

(c) ANNUAL REPORTS.—Not later than 1 year after the date of enactment of this Act, and annually thereafter for the next 4 years, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding an overview of the research conducted or supported under this section and any relevant findings. Such reports may include information about how the research and relevant findings under this section relate to other research efforts supported by other public or private entities.

SEC. 302. RESEARCH CENTERS FOR PATHOGENS OF PANDEMIC CONCERN.

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

"SEC. 447D. RESEARCH CENTERS FOR PATHOGENS OF PANDEMIC CONCERN.

''(a) IN GENERAL.—The Director of the Institute, in collaboration, as appropriate, with the directors of applicable institutes, centers, and divisions of the National Institutes of Health, the Assistant Secretary for Preparedness and Response, and the Director of the Biomedical Advanced Research and Development Authority, shall establish or continue a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic, through support for research centers.

''(b) USES OF FUNDS.—The Director of the Institute shall award funding through grants, contracts, or cooperative agreements to public or private entities to provide support for research centers described in subsection (a) for the purpose of—

''(1) conducting basic research through preclinical development of new medical products or technologies, including platform technologies, to address pathogens of pandemic concern;

''(2) identifying potential targets for therapeutic candidates, including antivirals, to treat such pathogens;

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

''(4) carrying out or supporting other research related to medical products to address such pathogens, as determined appropriate by the Director.

''(c) COORDINATION.—The Director of the Institute shall, as appropriate, provide for the coordination of activities among the centers described in subsection (a), including through—

''(1) facilitating the exchange of information and regular communication among the centers, as appropriate; and

''(2) requiring the periodic preparation and submission to the Director of reports on the activities of each center.

''(d) PRIORITY.—In awarding funding through grants, contracts, or cooperative agreements under subsection (a), the Director of the Institute shall, as appropriate, give priority to applicants with existing frameworks and partnerships, as applicable, to support the advancement of such research.

''(e) COLLABORATION.—The Director of the Institute shall—

''(1) collaborate with the heads of other appropriate Federal departments, agencies, and offices with respect to the identification of additional priority virus families and other viral pathogens with a significant potential to cause a pandemic; and

''(2) collaborate with the Director of the Biomedical Advanced Research and Development Authority with respect to the research conducted by centers described in subsection (a), including, as appropriate, providing any updates on the research advancements made by such centers, identifying any advanced research and development needs for such countermeasures, consistent with section 319L(a)(6), and taking into consideration existing manufacturing capacity and future capacity needs for such medical products or technologies, including platform technologies, supported by the centers described in subsection (a).

''(f) SUPPLEMENT, NOT SUPPLANT.—Any support received by a center described in subsection (a) under this section shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported.''.

SEC. 303. IMPROVING MEDICAL COUNTERMEASURE RESEARCH COORDINATION.

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

(1) in paragraph (24), by striking ''and'' at the end;

(2) in paragraph (25), by striking the period and inserting a semicolon; and

(3) by inserting after paragraph (25) the following:

''(26) shall consult with the Assistant Secretary for Preparedness and Response, the Director of the Biomedical Advanced Research and Development Authority, the Director of the Centers for Disease Control and Prevention, and the heads of other Federal agencies and offices, as appropriate, regarding research needs to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agent that may cause a public health emergency or other research needs related to emerging public health threats;''.

SEC. 304. ACCESSING SPECIMEN SAMPLES AND DIAGNOSTIC TESTS.

(a) IMPROVING RESEARCH AND DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR NOVEL PATHOGENS.—

(1) SAMPLE ACCESS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens or suitable surrogates for, or alternatives to, such pathogens as the Secretary determines appropriate to support public health preparedness and response activities or biomedical research for purposes of the development and validation, as applicable, of medical products to address emerging infectious diseases and for use to otherwise respond to emerging infectious diseases. Such policies and procedures shall take into account, as appropriate, any applicable existing Federal resources.

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

(A) the method for requesting such samples;

(B) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens, as appropriate, including applicable safeguard and security measures; and

(C) information required to be provided in order to receive such samples or suitable surrogates or alternatives.

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

"SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC TESTS.

''The Secretary may contract with public and private entities, as appropriate, to increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an emerging infectious disease with respect to which a public health emergency is declared under section 319, or that has significant potential to cause such a public health emergency.''.

Subtitle B—Improving Biosafety and Biosecurity

SEC. 311. IMPROVING CONTROL AND OVERSIGHT OF SELECT BIOLOGICAL AGENTS AND TOXINS.

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

(1) in subsection (b)(1), by amending subparagraph (A) to read as follows:

"(A) proper training, including with respect to notification requirements under this section, of—

"(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

"(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

"(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;";

(2) in subsection (e)(1), by striking ''(including the risk of use in domestic or international terrorism)'' and inserting ''(including risks posed by the release, theft, or loss of such agent or toxin, or use in domestic or international terrorism)'';

(3) in subsection (k)—

(A) by redesignating paragraphs (1) and (2) as paragraphs (2) and (3), respectively;

(B) by inserting before paragraph (2), as so redesignated, the following:

''(1) NOTIFICATION WITH RESPECT TO FEDERAL FACILITIES.—In the event of the release, loss, or theft of an agent or toxin listed by the Secretary pursuant to subsection (a)(1), or by the Secretary of Agriculture pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002, from or within a laboratory facility owned or operated by the Department of Health and Human Services, or other Federal laboratory facility subject to the requirements of this section, the Secretary, in a manner that does not compromise national security, shall—

''(A) not later than 72 hours after such event is reported to the Secretary, notify the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of such event, including—

''(i) the Federal laboratory facility in which such release, loss, or theft occurred; and

''(ii) the circumstances of such release, loss, or theft; and

''(B) not later than 14 days after such notification, update such Committees on—

''(i) any actions taken or planned by the Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and

''(ii) any actions taken or planned by the Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.''; and

(C) by amending paragraph (2), as so redesignated, to read as follows:

''(2) ANNUAL REPORT.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on an annual basis a report—

''(A) summarizing the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases), during the preceding fiscal year;

''(B) describing actions taken by the Secretary to address such incidents, such as any corrective action plans required and steps taken to promote adherence to, and compliance with, safety and security best practices, standards, and regulations; and

''(C) describing any gaps, challenges, or limitations with respect to ensuring that such safety and security practices are consistently applied and adhered to, and actions taken to address such gaps, challenges, or limitations.''; and

(4) in subsection (m), by striking ''fiscal years 2002 through 2007'' and inserting ''fiscal years 2023 through 2027''.

SEC. 312. STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES.

(a) STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES.—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Science

and Technology Policy, in consultation with relevant Federal agencies and departments, shall establish a strategy for the management, maintenance, and oversight of federally-owned laboratory facilities capable of operating at Biosafety Level 3 or 4, including equivalent classification levels. Such strategy shall include—

(1) a description of the roles and responsibilities of relevant Federal departments and agencies with respect to the management, maintenance, and oversight of Biosafety Level 3 or 4 laboratory facilities;

(2) an assessment of the needs of the Federal Government with respect to Biosafety Level 3 or 4 laboratory facilities;

(3) a summary of existing federally-owned Biosafety Level 3 or 4 laboratory facility capacity;

(4) a summary of other Biosafety Level 3 or 4 laboratory facility capacity established through Federal funds;

(5) a description of how the capacity described in paragraphs (3) and (4) addresses the needs of the Federal Government, including—

(A) how relevant Federal departments and agencies coordinate to provide access to appro-

priate laboratory facilities to reduce unnecessary duplication; and

(B) any gaps in such capacity related to such needs;

(6) a summary of plans that are in place for the maintenance of such capacity, as applicable and appropriate, including processes for determining whether to maintain or expand such capacity, and a description of how the Federal Government will address rapid changes in the need for such capacity during a public health emergency; and

(7) a description of how the heads of relevant Federal departments and agencies will coordinate to ensure appropriate oversight of federally-owned laboratory facility capacity and leverage such capacity, as appropriate, to fulfill the needs of multiple Federal departments and agencies in order to reduce unnecessary duplication and improve collaboration within the Federal Government.

SEC. 313. NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404O. NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of NIH, shall establish an advisory committee, to be known as the 'National Science Advisory Board for Biosecurity' (referred to in this section as the 'Board').

''(b) DUTIES.—

''(1) IN GENERAL.—The National Science Advisory Board for Biosecurity referred to in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) (referred to in this section as the 'Board') shall provide technical advice, guidance, or recommendations, to relevant Federal departments and agencies related to biosafety and biosecurity oversight of biomedical research, including—

''(A) oversight of federally-conducted or federally-supported dual use biomedical research, such as the review of policies or frameworks used to assess and appropriately manage safety and security risks associated with such research, taking into consideration national security concerns, the potential benefits of such research, considerations related to the research community, transparency, and public avail-

ability of information, and international research collaboration; and

''(B) continuing to carry out the activities required under section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417).

''(c) CONSIDERATIONS.—In carrying out the duties under subsection (b), the Board may consider strategies to improve the safety and security of biomedical research, including through—

''(1) leveraging or using new technologies and scientific advancements to reduce safety and security risks associated with such research and improve containment of pathogens; and

''(2) outreach to, and education and training of, researchers, laboratory personnel, and other appropriate individuals with respect to safety and security risks associated with such research and mitigation of such risks.

''(d) MEMBERSHIP.—The Board shall be composed of the following:

''(1) Non-voting, ex officio members, including the following:

''(A) At least one representative of each of the following:

''(i) The Department of Health and Human Services.

''(ii) The Department of Defense.

''(iii) The Department of Agriculture.

''(iv) The Department of Homeland Security.

''(v) The Department of Energy.

''(vi) The Department of State.

''(vii) The Office of Science and Technology Policy.

''(viii) The Office of the Director of National Intelligence.

''(B) Representatives of such other Federal departments or agencies as the Secretary determines appropriate to carry out the requirements of this section.

''(2) Individuals, appointed by the Secretary, with expertise in biology, infectious diseases, public health, ethics, national security, and other fields, as the Secretary determines appropriate, who shall serve as voting members.''.

(b) ORDERLY TRANSITION.—The Secretary of Health and Human Services shall take such steps as are necessary to provide for the orderly transition to the authority of the National Science Advisory Board for Bio-

security established under section 404O of the Public Health Service Act, as added by subsection (a), from any authority of the Board described in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417), as in effect on the day before the date of enactment of this Act.

(c) APPLICATION.—The requirements under section 404O of the Public Health Service Act, as added by subsection (a), related to the mission, activities, or functions of the National Science Advisory Board for Biosecurity shall not apply until the completion of any work undertaken by such Board before the date of enactment of this Act.

SEC. 314. RESEARCH TO IMPROVE BIOSAFETY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, as appropriate, conduct or support research to improve the safe conduct of biomedical research activities involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

(b) REPORT.—Not later than 5 years after the date of enactment of this Act, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on

Energy and Commerce of the House of Representatives regarding an overview of any research conducted or supported under this section, any relevant findings, and steps the Secretary is taking to disseminate any such findings to support the reduction of risks associated with biomedical research involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

SEC. 315. FEDERALLY-FUNDED RESEARCH WITH ENHANCED PATHOGENS OF PANDEMIC POTENTIAL.

(a) REVIEW AND OVERSIGHT OF ENHANCED PATHOGENS OF PANDEMIC POTENTIAL.—

(1) IN GENERAL.—The Director of the Office of Science and Technology Policy (referred to in this section as the ''Director''), in consultation with the heads of relevant Federal departments and agencies, shall—

(A) not later than 1 years after the date of enactment of this Act—

(i) continue or conduct a review of existing Federal policies related to research proposed for Federal funding that may be reasonably anticipated to involve the cre-

ation, transfer, or use of pathogens of pandemic potential; and

(ii) establish or update a Federal policy for the consistent review and oversight of such proposed research that appropriately considers the risks associated with, and potential benefits of, such research; and

(B) not less than every 4 years thereafter, review and update such policy, as necessary and appropriate, to ensure that such policy fully accounts for relevant research that may be reasonably anticipated to involve the creation, transfer, or use of enhanced pathogens of pandemic potential, takes into consideration the benefits of such research, and supports the mitigation of related risks.

(2) REQUIREMENTS.—The policy established pursuant to paragraph (1) shall include—

(A) a clear scope to support the consistent identification of research proposals subject to such policy by relevant Federal departments and agencies;

(B) a framework for such reviews that accounts for safety, security, and ethical consider-

ations related to the creation, transfer, or use of enhanced pathogens of pandemic potential;

(C) measures to enhance the transparency and public availability of information related to such research activities in a manner that does not compromise national security, the safety and security of such research activities, or any identifiable, sensitive information of relevant individuals; and

(D) consistent procedures across relevant Federal department and agencies to ensure that—

(i) proposed research that has been determined to have scientific and technical merit and may be subject to such policy is identified and referred for review;

(ii) subjected research activities conducted under an award, including activities undertaken by any subrecipients of such award, are monitored regularly throughout the project period to ensure compliance with such policy and the terms and conditions of such award; and

(iii) in the event that federally-funded research activities not subject to such pol-

icy produce unanticipated results related to the creation, transfer, or use of enhanced pathogens of pandemic potential, such research activities are identified and appropriately reviewed under such policy.

(3) CLARIFICATION.—Reviews required pursuant to this section shall be in addition to any applicable requirements for research project applications required under the Public Health Service Act, including reviews required under section 492 of such Act (42 U.S.C. 289a), as applicable, or other applicable laws.

(b) IMPLEMENTATION.—

(1) IN GENERAL.—The Director shall direct all heads of relevant Federal departments and agencies to update, modernize, or promulgate applicable implementing regulations and guidance to implement the requirements of this section.

(2) UPDATES.—Consistent with the requirements under subsection (a)(1)(B), the Director shall require all heads of relevant Federal departments and agencies to update such policies consistent with any changes to the policy established pursuant to subsection (a)(1).

Subtitle C—Preventing Undue Foreign Influence in Biomedical Research

SEC. 321. FOREIGN TALENT PROGRAMS.

The Secretary of Health and Human Services shall require disclosure of participation in foreign talent programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded through the Department of Health and Human Services.

SEC. 322. SECURING IDENTIFIABLE, SENSITIVE INFORMATION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in consultation with the Director of National Intelligence, the Secretary of State, the Secretary of Defense, and other national security experts, as appropriate, shall ensure that biomedical research supported or conducted by the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services involving the sequencing of human genomic information, and collection, analysis, or storage of identifiable, sensitive information, as defined in

section 301(d)(4) of the Public Health Service Act (42 U.S.C. 241(d)(4)), is conducted in a manner that appropriately considers national security risks, including national security implications related to potential misuse of such data. Not later than 1 year after the date of enactment of this Act, the Secretary shall ensure that the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services, working with the heads of agencies and national security experts, including the Office of the National Security within the Department of Health and Human Services—

(1) develop a comprehensive framework for assessing and managing such national security risks that includes—

(A) criteria for how and when to conduct risk assessments for projects that may have national security implications;

(B) security controls and training for researchers or entities, including peer reviewers, that manage or have access to such data; and

(C) methods to incorporate risk-reduction in the process for funding such projects that may have national security implications;

(2) not later than 1 year after the risk framework is developed under paragraph (1), develop and implement controls to—

(A) ensure that researchers or entities that manage or have access to such data have complied with the requirements of paragraph (1) and ongoing requirements with such paragraph; and

(B) ensure that data access committees reviewing data access requests for projects that may have national security risks, as appropriate, include members with expertise in current and emerging national security threats, in order to make appropriate decisions related to access to such identifiable, sensitive information; and

(3) not later than 2 years after the risk framework is developed under paragraph (1), update data access and sharing policies related to human genomic data, as appropriate, based on current and emerging national security threats.

(b) CONGRESSIONAL BRIEFING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall provide a briefing to the Committee on Health, Education, Labor, and Pensions and the Select Committee on

Intelligence of the Senate and the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the House of Representatives on the activities required under subsection (a).

SEC. 323. DUTIES OF THE DIRECTOR.

Section 402(b) in the Public Health Service Act (42 U.S.C. 282(b)), as amended by section 303, is further amended by inserting after paragraph (26) (as added by section 303) the following:

''(27) shall consult with the Director of the Office of National Security within the Department of Health and Human Services, the Assistant Secretary for Preparedness and Response, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other appropriate agencies on a regular basis, regarding biomedical research conducted or supported by the National Institutes of Health that may affect or be affected by matters of national security;

''(28) shall ensure that recipients of awards from the National Institutes of Health, and, as appropriate and practicable, entities collaborating with such recipients, have in place and are adhering to appropriate technology practices and policies for the security of identifiable, sensitive information, includ-

ing information collected, stored, or analyzed by domestic and non-domestic entities; and

''(29) shall ensure that recipients of awards from the National Institutes of Health are in compliance with the terms and conditions of such award, which may include activities to support awareness of, and compliance with, such terms and conditions by any subrecipients of the award.''.

SEC. 324. PROTECTING AMERICA'S BIOMEDICAL RESEARCH ENTERPRISE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in collaboration with Assistant to the President for National Security Affairs, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other relevant departments and agencies, and in consultation with research institutions and research advocacy organizations or other relevant experts, as appropriate, shall—

(1) identify ways to improve the protection of intellectual property and other proprietary information, as well as identifiable, sensitive information of participants in biomedical research and development, from national security risks and other applicable threats, including the identification of gaps in poli-

cies and procedures in such areas related to biomedical research and development supported by the Department of Health and Human Services and biomedical research supported by other agencies as applicable, and make recommendations to institutions of higher education or other entities that have traditionally received Federal funding for biomedical research to protect such information;

(2) identify or develop strategies to prevent, mitigate, and address national security threats in biomedical research and development supported by the Federal Government, including such threats associated with foreign talent programs, by countries seeking to exploit United States technology and other proprietary information as it relates to such biomedical research and development;

(3) identify national security risks and potential misuse of proprietary information, and identifiable, sensitive information of biomedical research participants and other applicable risks, including with respect to peer review, and make recommendations for additional policies and procedures to protect such information;

(4) develop a framework to identify areas of biomedical research and development supported by

the Federal Government that are emerging areas of interest for state actors and would compromise national security if they were to be subjected to undue foreign influence; and

(5) regularly review recommendations or policies developed under this section and make additional recommendations or updates, as appropriate.

(b) REPORT TO PRESIDENT AND TO CONGRESS.—Not later than 1 year after the date of enactment of this Act, the Secretary shall prepare and submit, in a manner that does not compromise national security, to the President and the Committee on Health, Education, Labor, and Pensions and the Select Committee on Intelligence of the Senate, the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the House of Representatives, and other congressional committees as appropriate, a report on the findings and recommendations pursuant to subsection (a).

SEC. 325. GAO STUDY.

(a) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall conduct a study to assess the extent to which the Department of Health and Human Services (referred to in this section as the ''Department'') utilizes or provides funding to entities that utilize such funds for

human genomic sequencing services or genetic services (as such term is defined in section 201(6) of the Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. 2000ff(6))) provided by entities, or subsidiaries of such entities, organized under the laws of a country or countries of concern, in the estimation of the Director of National Intelligence or the head of another Federal department or agency, as appropriate.

(b) CONSIDERATIONS.—In carrying out the study under this section, the Comptroller General shall—

(1) consider—

(A) the extent to which the country or countries of concern could obtain human genomic information of citizens and residents of the United States from such entities that sequence, analyze, collect, or store human genomic information and which the Director of National Intelligence or the head of another Federal department or agency reasonably anticipates may use such information in a manner inconsistent with the national security interests of the United States;

(B) whether the Department or recipient of such funds from the Department sought to provide funding to, or to use, domestic entities

with no such ties to the country or countries of concern for such purposes and any barriers to the use of domestic entities; and

(C) whether data use agreements, data security measures, and other such measures taken by the Department or recipient of such funds from the Department are sufficient to protect the identifiable, sensitive information of the people of the United States and the national security interests of the United States; and

(2) make recommendations to address any vulnerabilities to the United States national security identified, as appropriate.

(c) ESTIMATION.—In conducting the study under this section, the Comptroller General may, as appropriate and necessary to complete such study, investigate specific instances of such utilization of genetic sequencing services or genetic services, as described in subsection (a), to produce estimates of the potential prevalence of such utilization among entities in receipt of Departmental funds.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit a report on the study under this section, in a manner that does not compromise national security, to the Committee on Health, Education, Labor, and Pensions

and the Select Committee on Intelligence of the Senate, and the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the House of Representatives. The report shall be submitted in unclassified form, to the extent practicable, but may include a classified annex.

SEC. 326. REPORT ON PROGRESS TO ADDRESS UNDUE FOREIGN INFLUENCE.

Not later than 1 year after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce in the House of Representatives, in a manner that does not compromise national security, a report on actions taken by such Secretary—

(1) to address cases of noncompliance with disclosure requirements or research misconduct related to foreign influence, including—

(A) the number of potential noncompliance cases investigated by the National Institutes of Health or reported to the National Institutes of Health by a research institution, including relating to undisclosed research support, undis-

closed conflicts of interest or other conflicts of commitment, and peer review violations;

(B) the number of cases referred to the Office of Inspector General of the Department of Health and Human Services, the Office of National Security of the Department of Health and Human Services, the Federal Bureau of Investigation, or other law enforcement agencies;

(C) a description of enforcement actions taken for noncompliance related to undue foreign influence; and

(D) any other relevant information; and

(2) to prevent, address, and mitigate instances of noncompliance with disclosure requirements or research misconduct related to foreign influence.

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

SEC. 401. WARM BASE MANUFACTURING CAPACITY FOR MEDICAL COUNTERMEASURES.

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

(1) in subsection (a)(6)(B)—

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

(B) by inserting after clause (iii), the following:

''(iv) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products;''; and

(C) in clause (vi) (as so redesignated), by inserting ''manufacturing,'' after ''improvement,'';

(2) in subsection (b)—

(A) in the first sentence of paragraph (1), by inserting ''support for domestic manufacturing surge capacity and capabilities,'' after ''initiatives for innovation,''; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ''and'' at the end;

(ii) by redesignating subparagraph (C) as subparagraph (D); and

(iii) by inserting after subparagraph (B), the following:

''(C) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products; and'';

(3) in subsection (c)—

(A) in paragraph (2)(B), by inserting before the semicolon '', including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv)'';

(B) in paragraph (4)—

(i) in subparagraph (A)—

(I) in clause (i)—

(aa) in subclause (I), by striking ''and'' at the end; and

(bb) by adding at the end the following:

''(III) facilitating such communication, as appropriate, regarding manufacturing surge capacity and capabilities with respect to qualified countermeasures and qualified pandemic or epidemic products to prepare for, or respond to, a public health emergency or potential public health emergency; and

''(IV) facilitating such communication, as appropriate and in a manner that does not compromise national security, with respect to potential eligibility for the material threat medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act;'';

(II) in clause (ii)(III), by striking ''and'' at the end;

(III) by redesignating clause (iii) as clause (iv); and

(IV) by inserting after clause (ii), the following:

''(iii) communicate regularly with entities in receipt of an award pursuant to subparagraph (B)(v), and facilitate communication between such entities and other entities in receipt of an award pursuant to subparagraph (B)(iv), as appropriate, for purposes of planning and response regarding the availability of countermeasures and the maintenance of domestic manufacturing surge capacity and capabilities, including any planned uses of such capacity and capabilities in the near- and mid-term, and identification of any significant challenges related to the long-term maintenance of such capacity and capabilities; and'';

(ii) in subparagraph (B)—

(I) in clause (iii), by striking ''and'' at the end;

(II) in clause (iv), by striking the period and inserting ''; and''; and

(III) by adding at the end the following:

''(v) award contracts, grants, and cooperative agreements and enter into other

transactions to support, maintain, and improve domestic manufacturing surge capacity and capabilities, including through supporting flexible or advanced manufacturing, to ensure that additional capacity is available to rapidly manufacture products that are or may become qualified countermeasures or qualified pandemic or epidemic products in the event of a public health emergency declaration or significant potential for a public health emergency.'';

(iii) in subparagraph (C)—

(I) in clause (i), by striking ''and'' at the end;

(II) in clause (ii), by striking the period at the end and inserting ''; and''; and

(III) by adding at the end the following:

''(iii) consult with the Commissioner of Food and Drugs, pursuant to section 565(b)(2) of the Federal Food, Drug, and Cosmetic Act, to ensure that facilities performing manufacturing, pursuant to an award under subparagraph (B)(v), are in

compliance with applicable requirements under such Act and this Act, as appropriate, including current good manufacturing practice pursuant to section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act; and'';

(iv) in subparagraph (D)(i), by inserting '', including to improve manufacturing capacities and capabilities for medical countermeasures'' before the semicolon;

(v) in subparagraph (E)(ix), by striking ''2023'' and inserting ''2028''; and

(vi) by adding at the end the following:

''(G) ANNUAL REPORTS BY AWARD RECIPIENTS.—As a condition of receiving an award under subparagraph (B)(v), a recipient shall develop and submit to the Secretary annual reports related to the maintenance of such capacity and capabilities, including ensuring that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary.''; and

(C) in paragraph (5), by adding at the end the following:

''(H) SUPPORTING WARM-BASE AND SURGE CAPACITY AND CAPABILITIES.—Pursuant to an award under subparagraph (B)(v), the Secretary may make payments for activities necessary to maintain domestic manufacturing surge capacity and capabilities supported under such award to ensure that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency or otherwise address threats that pose a significant level of risk to national security. The Secretary may support the utilization of such capacity and capabilities under awards for countermeasure and product advanced research and development, as appropriate, to provide for the maintenance of such capacity and capabilities.'';

and

(4) in subsection (f)—

(A) in paragraph (1), by striking ''Not later than 180 days after the date of enactment of this subsection'' and inserting ''Not later than 180 days after the date of enactment of the PREVENT Pandemics Act'';

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking ''this subsection'' and inserting ''the PREVENT Pandemics Act'';

(ii) in subparagraph (B), by striking ''and'' at the end; and

(iii) in subparagraph (C), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(D) plans for the near-, mid-, and long-term sustainment of manufacturing activities carried out under this section, including such activities pursuant to subsection (c)(5)(H), specific actions to regularly assess the ability of recipients of an award under subsection (c)(4)(B)(v) to rapidly manufacture countermeasures as required by the Secretary, and recommendations to address challenges, if any, related to such activities.''.

SEC. 402. SUPPLY CHAIN CONSIDERATIONS FOR THE STRATEGIC NATIONAL STOCKPILE.

Subclause (II) of section 319F–2(a)(2)(B)(i) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(2)(B)(i)) is amended to read as follows:

"(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including—

"(aa) consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies on the health care system; and

"(bb) an assessment of the current supply chain for such products, including information on supply chain redundancies, any known domestic manufacturing capacity for such products, and any related vulnerabilities;".

SEC. 403. STRATEGIC NATIONAL STOCKPILE EQUIPMENT MAINTENANCE.

Subparagraph (D) of section 319F–2(a)(3) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)) is amended to read as follows:

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

''(i) emerging threats, advanced technologies, and new countermeasures are adequately considered;

''(ii) the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment; and

''(iii) such contents are in working condition or usable, as applicable, and are ready for deployment, which may include conducting maintenance services on such contents of the stockpile and disposing of such contents that are no longer in working condition, or usable, as applicable;''.

SEC. 404. IMPROVING TRANSPARENCY AND PREDICTABILITY OF PROCESSES OF THE STRATEGIC NATIONAL STOCKPILE.

(a) GUIDANCE.—Not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue guidance describing the processes by

which the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), or otherwise distributes medical countermeasures, as applicable, to States, territories, Indian Tribes and Tribal organizations (as such terms are defined under section 4 of the Indian Self-Determination and Education Assistance Act), and other applicable entities. Such guidance shall include information related to processes by which to request access to the contents of the Strategic National Stockpile, factors considered by the Secretary when making deployment or distribution decisions, and processes and points of contact through which entities may contact the Secretary to address any issues related to products requested or received by such entity from the stockpile, and on other relevant topics.

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

(1) in subparagraph (I), by striking ''and'' at the end;

(2) in subparagraph (J), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(K) convene meetings, not less than once per year, with representatives from State, local, and Tribal health departments or officials, relevant industries, other Federal agencies, and other appropriate stakeholders, in a manner that does not compromise national security, to coordinate and share information related to maintenance and use of the stockpile, including a description of future countermeasure needs and additions, modifications, and replenishments of the contents of the stockpile, and considerations related to the manufacturing and procurement of products consistent with the requirements of the Buy American Act of 1933, as appropriate.''.

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

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

(1) in subsection (a)—

(A) in paragraph (3)(F), by striking ''as required by the Secretary of Homeland Security'' and inserting ''at the discretion of the Secretary, in consultation with, or at the request of, the Secretary of Homeland Security,'';

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

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

''(5) VENDOR-MANAGED INVENTORY AND WARM-BASE SURGE CAPACITY.—

''(A) IN GENERAL.—For the purposes of maintaining the stockpile under paragraph (1) and carrying out procedures under paragraph (3), the Secretary may enter into contracts or cooperative agreements with vendors, which may include manufacturers or distributors of medical products, with respect to medical products intended to be delivered to the ownership of the Federal Government. Each such contract or cooperative agreement shall be subject to such terms and conditions as the Secretary may specify, including terms and conditions with respect to—

''(i) procurement, maintenance, storage, and delivery of reserve amounts of products under such contract or cooperative agreement, which may consider, as appropriate, costs of transporting and handling such products; and

"(ii) maintenance of domestic manufacturing capacity and capabilities of such products to ensure additional reserved production capacity and capabilities are available, and that such capacity and capabilities are able to support the rapid manufacture, purchase, storage, and delivery of such products, as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency.

"(B) REPORT.—Not later than 2 years after the date of enactment of the PREVENT Pandemics Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on any contracts or cooperative agreements entered into under subparagraph (A) for purposes of establishing and maintaining vendor-managed inventory or reserve manufacturing capacity and capabilities for products intended for the stockpile, including a description of—

"(i) the amount of each award;

"(ii) the recipient of each award;

"(iii) the product or products covered through each award; and

"(iv) how the Secretary works with each recipient to ensure situational awareness related to the manufacturing capacity for, or inventory of, such products and coordinates the distribution and deployment of such products, as appropriate and applicable."; and

(D) in subparagraph (A) of paragraph (6), as so redesignated—

(i) in clause (viii), by striking "; and" and inserting a semicolon;

(ii) in clause (ix), by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(x) with respect to reports issued in 2027 or any subsequent year, an assessment of selected contracts or cooperative agreements entered into pursuant to paragraph (5)."; and

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

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

SEC. 406. REIMBURSEMENT FOR CERTAIN SUPPLIES.

Paragraph (7) of section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as so redesignated by section 405(a)(1)(B), is amended to read as follows:

''(7) REIMBURSEMENT FOR CERTAIN SUPPLIES.—

''(A) IN GENERAL.—The Secretary may, at appropriate intervals, make available for purchase excess contents procured for, and maintained within, the stockpile under paragraph (1) to any Federal agency or State, local, or Tribal government. The Secretary shall make such contents available for purchase only if—

''(i) such contents are in excess of what is required for appropriate maintenance of such stockpile;

"(ii) the Secretary determines that the costs for maintaining such excess contents are not appropriate to expend to meet the needs of the stockpile; and

"(iii) the Secretary determines that such action does not compromise national security and is in the national interest.

"(B) REIMBURSEMENT AND COLLECTION.—The Secretary may require reimbursement for contents that are made available under subparagraph (A), in an amount that reflects the cost of acquiring and maintaining such contents and the costs incurred to make available such contents in the time and manner specified by the Secretary. Amounts collected under this subsection shall be credited to the appropriations account or fund that incurred the costs to procure such contents, and shall remain available, without further appropriation, until expended, for the purposes of the appropriation account or fund so credited.

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

"(D) REPORT.—Not later than 2 years after the date of enactment of the PREVENT Pandemics Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the use of the authority provided under this paragraph, including details of each action taken pursuant to this paragraph, the account or fund to which any collected amounts have been credited, and how the Secretary has used such amounts.

"(E) SUNSET.—The authority under this paragraph shall terminate on September 30, 2025.".

SEC. 407. ACTION REPORTING ON STOCKPILE DEPLETION.

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

"(h) STOCKPILE DEPLETION REPORTING.—The Secretary shall, not later than 30 days after the deployment of contents of the Strategic National Stockpile under section 319F–2(a) to respond to a public health emergency

declared by the Secretary under this section or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and every 30 days thereafter until the expiration or termination of such public health emergency, emergency, or major disaster, submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on—

''(1) the deployment of the contents of the stockpile in response to State, local, and Tribal requests;

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

''(3) plans to replenish such products, as appropriate, including related timeframes and any barriers or limitations to replenishment.''.

SEC. 408. PROVISION OF MEDICAL COUNTERMEASURES TO INDIAN PROGRAMS AND FACILITIES.

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

(1) in subparagraph (C), by striking ''and local'' and inserting ''local, and Tribal''; and

(2) in subparagraph (J), by striking ''and local'' and inserting ''local, and Tribal''.

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

''SEC. 319F–5. PROVISION OF MEDICAL COUNTERMEASURES TO INDIAN PROGRAMS AND FACILITIES.

''In the event that the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a), or otherwise distributes medical countermeasures to States to respond to a public health emergency declared by the Secretary under section 319, the Secretary shall, in consultation with the applicable States, make such contents or countermeasures directly available to Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), which may include through health programs or facilities operated by the Indian Health Service, that are affected by such public health emergency.''.

SEC. 409. GRANTS FOR STATE STRATEGIC STOCKPILES.

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

''(i) PILOT PROGRAM TO SUPPORT STATE MEDICAL STOCKPILES.—

''(1) IN GENERAL.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, shall award grants or cooperative agreements to not fewer than 5 States, or consortia of States, with consideration given to distribution among the geographical regions of the United States, to establish, expand, or maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies determined by the State to be necessary to respond to a public health emergency declared by the Governor of a State or by the Secretary under section 319, or a major disaster or emergency declared by the President under section 401 or 501, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, in order to support the preparedness goals described in paragraphs (2) through (6) and (8) of section 2802(b).

''(2) REQUIREMENTS.—

''(A) APPLICATION.—To be eligible to receive an award under paragraph (1), an entity

shall prepare, in consultation with appropriate health care entities and health officials within the jurisdiction of such State or States, and submit to the Secretary an application that contains such information as the Secretary may require, including—

"(i) a plan for such stockpile, consistent with paragraph (4), including a description of the activities such entity will carry out under the agreement and an outline of proposed expenses; and

"(ii) a description of how such entity will coordinate with relevant entities in receipt of an award under section 319C–1 or 319C–2 pursuant to paragraph (4), including through promoting alignment between the stockpile plan established pursuant to clause (i) and applicable plans that are established by such entity pursuant to section 319C–1 or 319C–2.

"(B) MATCHING FUNDS.—

"(i) Subject to clause (ii), the Secretary may not make an award under this subsection unless the applicant agrees, with respect to the costs to be incurred by

the applicant in carrying out the purpose described in this subsection, to make available non-Federal contributions toward such costs in an amount equal to—

"(I) for each of fiscal years 2023 and 2024, not less than $1 for each $20 of Federal funds provided in the award; and

"(II) for fiscal year 2025 and each fiscal year thereafter, not less than $1 for each $10 of Federal funds provided in the award.

"(ii) WAIVER.—The Secretary may, upon the request of a State, waive the requirement under clause (i), in whole or in part, if the Secretary determines that extraordinary economic conditions in the State in the fiscal year involved or in the previous fiscal year justify the waiver. A waiver provided by the Secretary under this subparagraph shall apply only to the fiscal year involved.

"(C) ADMINISTRATIVE EXPENSES.—Not more than 10 percent of amounts received by an entity pursuant to an award under this sub-

section may be used for administrative expenses.

''(3) LEAD ENTITY.—An entity in receipt of an award under paragraph (1) may designate a lead entity, which may be a public or private entity, as appropriate, to manage the stockpile at the direction of the State or consortium of States.

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

''(A) purchase, store, and maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies to be used during a public health emergency, major disaster, or emergency described in paragraph (1), in such numbers, types, and amounts as the entity determines necessary, consistent with such entity's stockpile plan established pursuant to paragraph (2)(A)(i);

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

"(C) replenish and make necessary additions or modifications to the contents of such stockpile, including to address potential depletion;

"(D) in consultation with Federal, State, and local officials, take into consideration the availability, deployment, dispensing, and administration requirements of medical products within the stockpile;

"(E) ensure that procedures are followed for inventory management and accounting, and for the physical security of the stockpile, as appropriate;

"(F) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that, to the extent practicable, new technologies and medical products are considered;

"(G) carry out exercises, drills, and other training for purposes of stockpile deployment, dispensing, and administration of medical products, and for purposes of assessing the capability of such stockpile to address the medical supply needs of public health emergencies, major disasters, or other emergencies described in paragraph (1) of varying types and scales,

which may be conducted in accordance with requirements related to exercises, drills, and other training for recipients of awards under section 319C–1 or 319C–2, as applicable; and

''(H) carry out other activities related to the State strategic stockpile as the entity determines appropriate, to support State efforts to prepare for, and respond to, public health threats.

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

''(6) GUIDANCE FOR STATES.—Not later than 180 days after the date of enactment of this subsection, the Secretary, in consultation with States, health officials, and other relevant stakeholders, as appropriate, shall issue guidance, and update such guidance as appropriate, for States related to maintaining and replenishing a stockpile of medical products, which may include strategies and best practices related to—

''(A) types of medical products and medical supplies that are critical to respond to public health emergencies, and may be appropriate

for inclusion in a stockpile by States, with consideration of threats that require the large-scale and simultaneous deployment of stockpiles, including the stockpile maintained by the Secretary pursuant to subsection (a), and long-term public health and medical response needs;

''(B) appropriate management of the contents of a stockpile, including management by vendors of reserve amounts of medical products and supplies intended to be delivered to the ownership of the State and appropriate disposition of excess products, as applicable; and

''(C) the procurement of medical products and medical supplies consistent with the Buy American Act of 1933.

''(7) TECHNICAL ASSISTANCE.—The Secretary shall provide assistance to States, including technical assistance, as appropriate, in establishing, maintaining, improving, and utilizing a medical stockpile, including appropriate inventory management and disposition of products.

''(8) REPORTING.—

''(A) STATE REPORTS.—Each entity receiving an award under paragraph (1) shall update, as appropriate, the plan established pur-

suant to paragraph (2)(A)(i) and submit to the Secretary an annual report on implementation of such plan, including any changes to the contents of the stockpile supported under such award. The Secretary shall use information obtained from such reports to inform the maintenance and management of the Strategic National Stockpile pursuant to subsection (a).

''(B) REPORTS TO CONGRESS.—Not later than 1 year after the initial issuance of awards pursuant to paragraph (1), and annually thereafter for the duration of the program established under this subsection, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such program, including—

''(i) Federal and State expenditures to support stockpiles under such program;

''(ii) activities conducted pursuant to paragraph (4); and

''(iii) any additional information from the States that the Secretary determines relevant.

"(9) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2023 through 2028.".

(b) GAO REPORT.—Not later than 3 years after the date on which awards are first issued pursuant to subsection (i)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b), as added by subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the State stockpiles established or maintained pursuant to this section. Such report shall include an assessment of—

(1) coordination and communication between the Secretary of Health and Human Services and entities in receipt of an award under this section, or a lead entity designated by such entity;

(2) technical assistance provided by the Secretary of Health and Human Services to such entities; and

(3) the impact of such stockpiles on the ability of the State to prepare for and respond to a public health emergency, major disaster, or other emergency described in subsection (i)(1) of section 319F–

2 of the Public Health Service Act (42 U.S.C. 247d–6b), as added by subsection (a), including the availability and distribution of items from such State stockpile to health care entities and other applicable entities.

TITLE V—ENHANCING DEVELOPMENT AND COMBATING SHORTAGES OF MEDICAL PRODUCTS

Subtitle A—Development and Review

SEC. 501. ADVANCING QUALIFIED INFECTIOUS DISEASE PRODUCT INNOVATION.

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

(1) in subsection (c)—

(A) in paragraph (2), by striking ''; or'' and inserting '';'';

(B) in paragraph (3), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(4) an application pursuant to section 351(a) of the Public Health Service Act.'';

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

(3) by amending subsection (g) to read as follows:

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means a drug, including an antibacterial or antifungal drug or a biological product, for human use that—

''(1) acts directly on bacteria or fungi or on substances produced by such bacteria or fungi; and

''(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

''(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(B) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) PRIORITY REVIEW.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by inserting ''of this Act, or section 351(a) of the Public Health Service Act, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness'' before the period.

SEC. 502. MODERNIZING CLINICAL TRIALS.

(a) CLARIFYING THE USE OF DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue or revise draft guidance regarding the appropriate use of validated digital health technologies in clinical trials to help improve recruitment for, retention in, participation in, and data collection during, clinical trials, and provide for novel clinical trial designs utilizing such technology for purposes of supporting the development of, and review of applications for, drugs and devices. Not later than 18 months after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(2) CONTENT.—The guidance described in paragraph (1) shall include—

(A) recommendations for data collection methodologies by which sponsors may incorporate the use of digital health technologies in clinical trials to collect data remotely from trial participants;

(B) considerations for privacy and security protections for data collected during a clinical trial, including—

(i) recommendations for the protection of trial participant data that is collected or used in research, using digital health technologies;

(ii) compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), subpart B of part 50 of title 21, Code of Federal Regulations, subpart C of part 56 of title 21, Code of Federal Regulations, the Federal policy for the protection of human subjects under subpart A of part 46 of title 45, Code of Federal Regulations (commonly known as the ''Common Rule''), and part 2 of title 42, Code of Federal Regulations (or any successor regulations); and

(iii) recommendations for protection of clinical trial participant data against cybersecurity threats, as applicable;

(C) considerations on data collection methods to help increase recruitment of clinical trial participants and the level of participation of such participants, reduce burden on clinical trial participants, and optimize data quality;

(D) recommendations for the use of electronic methods to obtain informed consent from clinical trial participants, taking into consideration applicable Federal law, including subpart B of part 50 of title 21, Code of Federal Regulations (or successor regulations), and, as appropriate, State law;

(E) best practices for communication and early engagement between sponsors and the Secretary on the development of data collection methods;

(F) the appropriate format to submit such data to the Secretary;

(G) a description of the manner in which the Secretary may assess or evaluate data collected through digital health technologies to support the development of the drug or device;

(H) recommendations regarding the data and information needed to demonstrate that a digital health technology is fit-for-purpose for a

clinical trial, and a description of how the Secretary will evaluate such data and information; and

(I) recommendations for increasing access to, and the use of, digital health technologies in clinical trials to facilitate the inclusion of diverse and underrepresented populations, as appropriate, including considerations for access to, and the use of, digital health technologies in clinical trials by people with disabilities and pediatric populations.

(b) ADVANCING DECENTRALIZED CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue or revise draft guidance to provide recommendations to clarify and advance the use of decentralized clinical trials to support the development of drugs and devices and help improve trial participant engagement and advance the use of flexible and novel clinical trial designs. Not later than 18 months after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(2) CONTENT.—The guidance described in paragraph (1) shall include—

(A) recommendations for methods of remote data collection, including trial participant experience data, though the use of digital health technologies, telemedicine, local laboratories, local health care providers, or other options for data collection;

(B) considerations for sponsors to minimize or reduce burdens for clinical trial participants associated with participating in a clinical trial, such as the use of digital technologies, telemedicine, local laboratories, local health care providers, or other data collection or assessment options, health care provider home visits, direct-to-participant shipping of investigational drugs and devices, and electronic informed consent, as appropriate;

(C) recommendations regarding conducting decentralized clinical trials to facilitate and encourage diversity among the clinical trial participants, as appropriate;

(D) recommendations for strategies and methods for recruiting, retaining, and engaging with clinical trial participants, including com-

munication regarding the role of trial participants and community partners to facilitate clinical trial recruitment and engagement, including with respect to diverse and underrepresented populations, as appropriate;

(E) considerations for review and oversight by sponsors and institutional review boards, including remote trial oversight;

(F) recommendations for decentralized clinical trial protocol designs and processes for evaluating such proposed trial designs;

(G) recommendations for digital health technology and other remote assessment tools that may support decentralized clinical trials, including guidance on appropriate technological platforms and tools, data collection and use, data integrity, and communication to clinical trial participants through such technology;

(H) a description of the manner in which the Secretary will assess or evaluate data collected within a decentralized clinical trial to support the development of the drug or device, if the manner is different from that used for a non-decentralized trial;

(I) considerations for sponsors to validate digital technologies and establish appropriate clinical endpoints for use in decentralized trials;

(J) considerations for privacy and security of personally identifiable information of trial participants; and

(K) considerations for conducting clinical trials using centralized approaches in conjunction with decentralized approaches.

(c) SEAMLESS AND CONCURRENT CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue or revise draft guidance on the use of seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of applications for drugs, as appropriate. Not later than 18 months after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(2) CONTENT.—The guidance described in paragraph (1) shall include—

(A) recommendations on the use of expansion cohorts and other seamless clinical trial de-

signs to assess different aspects of product candidates in one continuous trial, including how such clinical trial designs can be used as part of meeting the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) recommendations on the use of clinical trial designs that involve the concurrent conduct of different or multiple clinical trial phases, and the concurrent conduct of preclinical testing, to expedite the development of new drugs and facilitate the timely collection of data;

(C) recommendations for how to streamline trial logistics and facilitate the efficient collection and analysis of clinical trial data, including any planned interim analyses and how such analyses could be used to streamline the product development and review processes;

(D) considerations to assist sponsors in ensuring the rights, safety, and welfare of clinical trial participants, maintaining compliance with good clinical practice regulations, minimizing risks to clinical trial data integrity, and ensuring the reliability of clinical trial results;

(E) recommendations for communication and early engagement between sponsors and the Food and Drug Administration on the development of seamless, concurrent, or other adaptive trial designs, including review of, and feedback on, clinical trial protocols; and

(F) a description of the manner in which the Secretary will assess or evaluate data collected through seamless, concurrent, or other adaptive trial designs to support the development of the drug.

(d) INTERNATIONAL HARMONIZATION.—The Secretary shall work with foreign regulators pursuant to memoranda of understanding or other arrangements governing the exchange of information to facilitate international harmonization of the regulation and use of decentralized clinical trials, digital technology in clinical trials, and seamless, concurrent, and other adaptive or innovative clinical trial designs.

SEC. 503. ACCELERATING COUNTERMEASURE DEVELOPMENT AND REVIEW.

Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended by adding at the end the following:

''(h) ACCELERATING COUNTERMEASURE DEVELOPMENT AND REVIEW DURING AN EMERGENCY.—

''(1) ACCELERATION OF COUNTERMEASURE DEVELOPMENT AND REVIEW.—The Secretary may, at the request of the sponsor of a countermeasure, during a domestic, military, or public health emergency or material threat described in section 564A(a)(1)(C), expedite the development and review of countermeasures that are intended to address such domestic, military, or public health emergency or material threat for approval, licensure, clearance, or authorization under this title or section 351 of the Public Health Service Act.

''(2) ACTIONS.—The actions to expedite the development and review of a countermeasure under paragraph (1) may include the following:

''(A) Expedited review of submissions made by sponsors of countermeasures to the Food and Drug Administration, including rolling submissions of countermeasure applications and other submissions.

''(B) Expedited and increased engagement with sponsors regarding countermeasure development and manufacturing, including—

''(i) holding meetings with the sponsor and the review team and providing timely advice to, and interactive communication with, the sponsor regarding the development of the countermeasure to ensure that the development program to gather the nonclinical and clinical data necessary for approval, licensure, clearance, or authorization is as efficient as practicable;

''(ii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iii) assigning a cross-disciplinary project lead for the review team to facilitate;

''(iv) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; and

''(v) streamlining the review of approved, licensed, cleared, or authorized countermeasures to treat or prevent new or

emerging threats, including the review of any changes to such countermeasures.

''(C) Expedited issuance of guidance documents and publication of other regulatory information regarding countermeasure development and manufacturing.

''(D) Other steps to expedite the development and review of a countermeasure application submitted for approval, licensure, clearance, or authorization, as the Secretary determines appropriate.

''(3) LIMITATION OF EFFECT.—Nothing in this subsection shall be construed to require the Secretary to grant, or take any other action related to, a request of a sponsor to expedite the development and review of a countermeasure for approval, licensure, clearance, or authorization under paragraph (1).''.

SEC. 504. THIRD PARTY TEST EVALUATION DURING EMERGENCIES.

(a) IN GENERAL.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as amended by section 503, is further amended by adding at the end the following:

''(i) THIRD PARTY EVALUATION OF TESTS USED DURING AN EMERGENCY.—

''(1) IN GENERAL.—For purposes of conducting evaluations regarding whether an in vitro diagnostic product (as defined in section 809.3 of title 21, Code of Federal Regulations (or any successor regulations)) for which a request for emergency use authorization is submitted under section 564 meets the criteria for issuance of such authorization, the Secretary may, as appropriate, consult with persons with appropriate expertise with respect to such evaluations or enter into cooperative agreements or contracts with such persons under which such persons conduct such evaluations and make such recommendations, including, as appropriate, evaluations and recommendations regarding the scope of authorization and conditions of authorization.

''(2) REQUIREMENTS REGARDING EVALUATIONS AND RECOMMENDATIONS.—

''(A) IN GENERAL.—In evaluating and making recommendations to the Secretary regarding the validity, accuracy, and reliability of in vitro diagnostic products, as described in paragraph (1), a person shall consider and document whether the relevant criteria under sub-

section (c)(2) of section 564 for issuance of authorization under such section are met with respect to the in vitro diagnostic product.

''(B) WRITTEN RECOMMENDATIONS.—Recommendations made by a person under this subsection shall be submitted to the Secretary in writing, and shall include the reasons for such recommendation and other information that may be requested by the Secretary.

''(3) RULE OF CONSTRUCTION.— Nothing in this subsection shall be construed to require the Secretary to consult with, or enter into cooperative agreements or contracts with, persons as described in paragraph (1) for purposes of authorizing an in vitro diagnostic product or otherwise affecting the emergency use authorization authorities under this section or section 564.''.

(b) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall issue draft guidance on consultations with persons under subsection (i) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as added by subsection (a), including considerations concerning conflicts of interest, compensation ar-

rangements, and information sharing. Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

SEC. 505. FACILITATING THE USE OF REAL WORLD EVIDENCE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue or revise existing guidance on considerations for the use of real world data and real world evidence to support regulatory decision-making, as follows:

(1) With respect to drugs, such guidance shall address the use of such data and evidence to support the approval of a drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product application under section 351 of the Public Health Service Act (42 U.S.C. 262), or to support an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public Health Service Act. Such guidance shall include considerations for the inclusion, in such applications, of real world data and real world evidence obtained as a result of the use of drugs authorized for emergency use under section 564 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and considerations for standards and methodologies for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

(2) With respect to devices, such guidance shall address the use of such data and evidence to support the approval, clearance, or classification of a device pursuant to an application or submission submitted under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f)(2), 360e), or to support an investigational use exemption under section 520(g) of such Act (21 U.S.C. 360j(g)). Such guidance shall include considerations for the inclusion, in such applications, submissions, or requests, of real world data and real world evidence obtained as a result of the use of devices authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and considerations for standards and methodologies for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

SEC. 506. PLATFORM TECHNOLOGIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506J of such Act (21 U.S.C. 356j) the following:

"SEC. 506K. PLATFORM TECHNOLOGIES.

"(a) IN GENERAL.—The Secretary shall establish a process for the designation of platform technologies that meet the criteria described in subsection (b).

"(b) CRITERIA.—A platform technology incorporated within or utilized by a drug is eligible for designation as a designated platform technology under this section if—

"(1) the platform technology is incorporated in, or utilized by, a drug approved under section 505 of this Act or a biological product licensed under section 351 of the Public Health Service Act;

"(2) preliminary evidence submitted by the sponsor of the approved or licensed drug described in paragraph (1), or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and

"(3) data or information submitted by the applicable person under paragraph (2) indicates that

incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review processes.

''(c) REQUEST FOR DESIGNATION.—A person may request the Secretary designate a platform technology as a designated platform technology concurrently with, or at any time after, submission under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act for the investigation of a drug that incorporates or utilizes the platform technology that is the subject of the request.

''(d) DESIGNATION.—

''(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the platform technology that is the subject of the request meets the criteria described in subsection (b).

''(2) DESIGNATION.—If the Secretary determines that the platform technology meets the criteria described in subsection (b), the Secretary shall designate the platform technology as a designated platform technology and may expedite the development and review of any subsequent application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug

that uses or incorporates the platform technology pursuant to subsection (e), as appropriate.

''(3) DETERMINATION NOT TO DESIGNATE.—If the Secretary determines that the platform technology does not meet the criteria under subsection (b), the Secretary shall include with the determination not to designate the technology a written description of the rationale for such determination.

''(4) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation made under paragraph (2), if the Secretary determines that the designated platform technology no longer meets the criteria described in subsection (b). The Secretary shall communicate the determination to revoke a designation to the requesting sponsor in writing, including a description of the rationale for such determination.

''(5) APPLICABILITY.—Nothing in this section shall prevent a product that uses or incorporates a designated platform technology from being eligible for expedited approval pathways if it is otherwise eligible under this Act or the Public Health Service Act.

''(e) ACTIONS.—The Secretary may take actions to expedite the development and review of an application for

a drug that incorporates or utilizes a designated platform technology, including—

''(1) engaging in early interactions with the sponsor to discuss the use of the designated platform technology and what is known about such technology, including data previously submitted that is relevant to establishing, as applicable, safety or efficacy under section 505(b) of this Act or safety, purity, or potency under section 351(a) of the Public Health Service Act;

''(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug that proposes to use the designated platform technology to ensure that the development program designed to gather data necessary for approval or licensure is as efficient as practicable, which may include holding meetings with the sponsor and the review team throughout the development of the drug; and

''(3) considering inspectional findings, including prior findings, related to the manufacture of a drug that incorporates or utilizes the designated platform technology.

''(f) LEVERAGING DATA FROM DESIGNATED PLATFORM TECHNOLOGIES.—The Secretary shall, consistent

with applicable standards for approval, authorization, or licensure under this Act and section 351(a) of the Public Health Service Act, allow the sponsor of an application under section 505(b) of this Act or section 351(a) of the Public Health Service Act or a request for emergency use authorization under section 564, in order to support approval, licensure, or authorization, to reference or rely upon data and information within such application or request that incorporates or utilizes the same or substantially similar platform technology designated under subsection (d), provided that—

''(1) such data and information was submitted by the same sponsor, pursuant to the application for the drug with respect to which designation of the designated platform technology under subsection (d) was granted; or

''(2) the sponsor relying on such data and information received a right of reference to such data and information from the sponsor described in paragraph (1).

''(g) CHANGES TO A DESIGNATED PLATFORM TECHNOLOGY.—A sponsor of one or more applications approved under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug or biological product that incorporates or utilizes the same designated platform

technology may submit a single supplemental application for the same proposed changes to the designated platform technology that is applicable to more than one drug or biological product that incorporates or utilizes such designated platform technology that may be cross referenced in other applications incorporating such change. Such application may include one or more comparability protocols regarding how such changes to the platform technology would be made for each applicable application.

''(h) GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue draft guidance on the implementation of this section. Such guidance shall include examples of drugs that can be manufactured using platform technologies, including drugs that contain or consist of vectors and nucleic acids, information about the Secretary's review of platform technologies, information regarding submitting for designation, consideration for persons submitting a request for designation who has been granted a right of reference, the implementation of the designated platform technology designation program, efficiencies that may be achieved in the development and review of products that incorporate or utilize designated platform technologies, and recommendations and requirements for making and reporting manu-

facturing changes to a designated platform technology in accordance with section 506A.

''(i) DEFINITIONS.—For purposes of this section:

''(1) The term 'platform technology' means—

''(A) a technology incorporated into a drug or biological product, such as a nucleic acid sequence, molecular structure, mechanism of action, delivery method, or other technology the Secretary determines to be appropriate, or combination of any such technologies, that—

''(i) is essential to the characterization of the drug or biological product; and

''(ii) can be adapted for, or incorporated or utilized in, more than one drug or biological product sharing common structural elements; or

''(B) a standardized production or manufacturing process that is used to create or develop more than one drug sharing common structural elements that can be incorporated into multiple different drugs.

''(2) The term 'designated platform technology' means a platform technology that is designated as a platform technology under subsection (d).

''(j) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) alter the authority of the Secretary to approve drugs pursuant to section 505 of this Act or license biological products pursuant to section 351 of the Public Health Service Act, including standards of evidence and applicable conditions for approval or licensure under the applicable Act; or

''(2) confer any new rights with respect to the permissibility of a sponsor of an application for a drug product or biological product referencing information contained in another application submitted by the holder of an approved application under section 505(c) of this Act or of a license under section 351(a) of the Public Health Service Act.''.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, on the platform technology designation program under section 506K of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a). Such report shall include—

(1) the number of requests for designation under such program;

(2) the number of designations under such program issued, active, and revoked;

(3) the resources required to carry out such program (including the review time used for full-time equivalent employees);

(4) any efficiencies gained in the development, manufacturing, and review processes associated with such designations; and

(5) recommendations, if any, to strengthen the program to better leverage platform technologies that can be used in more than one drug and meet patient needs in a manner as timely as possible, taking into consideration the resources available to the Secretary of Health and Human Services for carrying out such program.

SEC. 507. INCREASING EUA DECISION TRANSPARENCY.

Section 564(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(h)(1)) is amended—

(1) by inserting ''on the internet website of the Food and Drug Administration and'' after ''promptly publish''; and

(2) by striking ''application under section 505(i), 512(j), or 520(g), even if such summary may

indirectly reveal the existence of such application'' and inserting ''application, request, or submission under this section or section 505(b), 505(i), 505(j), 512(b), 512(j), 512(n), 515, 510(k), 513(f)(2), 520(g), 520(m), 571, or 572 of this Act, or section 351(a) or 351(k) of the Public Health Service Act, even if such summary may reveal the existence of such an application, request, or submission, or data contained in such application, request, or submission''.

SEC. 508. IMPROVING FDA GUIDANCE AND COMMUNICATION.

(a) FDA REPORT AND IMPLEMENTATION OF GOOD GUIDANCE PRACTICES.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop, and publish on the website of the Food and Drug Administration—

(1) a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents, within centers, across the Food and Drug Administration, and across other applicable agencies; and

(2) a plan for implementation of such best practices, including across other applicable agencies, which shall address—

(A) streamlining development and review of guidance documents within centers and across the Food and Drug Administration;

(B) streamlining processes for regulatory submissions to the Food and Drug Administration, including through the revision or issuance of guidance documents; and

(C) implementing innovative guidance development processes and practices and transitioning or updating guidance issued during the COVID–19 public health emergency, as appropriate.

(b) REPORT AND IMPLEMENTATION OF FDA BEST PRACTICES FOR COMMUNICATING WITH EXTERNAL STAKEHOLDERS.—The Secretary, acting through the Commissioner of Food and Drugs, shall develop and publish on the website of the Food and Drug Administration a report on the practices of the Food and Drug Administration to broadly communicate with external stakeholders, other than through guidance documents, which shall include—

(1) a review of the types and methods of public communication that the Food and Drug Administration uses to communicate and interact with medical product sponsors and other external stakeholders;

(2) the identification of best practices for the efficient development, issuance, and use of such communications; and

(3) a plan for implementation of best practices for communication with external stakeholders, which shall address—

(A) advancing the use of innovative forms of communication, including novel document types and formats, to provide increased regulatory clarity to product sponsors and other stakeholders, and advancing methods of communicating and interacting with medical product sponsors and other external stakeholders, including the use of tools such as product submission templates, webinars, and frequently asked questions communications;

(B) streamlining processes for regulatory submissions; and

(C) implementing innovative communication development processes and transitioning or updating communication practices used during the COVID–19 public health emergency, as appropriate.

(c) CONSULTATION.—In developing and publishing the report and implementation plan under this section, the

Secretary shall consult with stakeholders, including researchers, academic organizations, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, clinical laboratories, health care providers, patient groups, and other appropriate stakeholders.

(d) MANNER OF ISSUANCE.—For purposes of carrying out this section, the Secretary may update an existing report or plan, and may combine the reports and implementation plans described in subsections (a) and (b) into one or more documents.

(e) TIMING.—The Secretary shall—

(1) not later than 1 year after the date of enactment of this Act, publish a draft of the reports and plans required under this section; and

(2) not later than 180 days after publication of the draft reports and plans under paragraph (1)—

(A) publish a final report and plan; and

(B) begin implementation of the best practices pursuant to such final plan.

SEC. 509. GAO STUDY AND REPORT ON HIRING CHALLENGES AT FDA.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and

the Committee on Energy and Commerce of the House of Representatives a report assessing the policies, practices, processes, and programs of the Food and Drug Administration with respect to hiring, recruiting, and retention, and the impact of such policies, practices, processes, and programs on the agency's ability to carry out its public health mission, including the agency's ability to respond to the COVID–19 public health emergency. Such report may involve policies, practices, processes, and programs of the Department of Health and Human Services and other agencies, as applicable.

(b) CONTENT OF REPORT.—The report required under subsection (a) shall include an assessment of—

(1) challenges related to the efficient hiring, recruiting, professional development, and retention of the Food and Drug Administration workforce, including, as applicable, the end-to-end hiring process, time to hire, multiple hiring authorities, salary levels, vacancy rates, and identification and availability of candidates with necessary expertise;

(2) causes of the challenges identified under paragraph (1), including an analysis of relevant policies, practices, processes, programs, organizational structure, resources, training, remote work capabilities, and data systems;

(3) challenges facing the Food and Drug Administration workforce, including with respect to workload, diversity, employee engagement, and morale;

(4) the impact of challenges identified under paragraphs (1) and (3) on operations of the Food and Drug Administration, including on meeting user fee agreement performance goals and inspection activities;

(5) any hiring or retention plans of the Food and Drug Administration, and progress towards implementation and the metrics to measure success of such plans;

(6) successful or efficient hiring policies or authorities, including any relevant hiring authorities that resulted in efficient hiring for vacant positions, such as temporary direct hiring authorities during the COVID–19 public health emergency response;

(7) whether policies, practices, processes, and programs related to hiring, recruiting, professional development, and retention are implemented consistently across the Food and Drug Administration;

(8) recommendations to address challenges identified, including recommendations regarding improvements to policies, practices, processes, and pro-

grams of the Food and Drug Administration with respect to hiring, recruiting, professional development, and retention; and

(9) challenges related to hiring, recruiting, and retaining a qualified workforce to meet public health emergency response needs, including any such challenges identified during the COVID–19 public health emergency.

Subtitle B—Mitigating Shortages

SEC. 511. ENSURING REGISTRATION OF FOREIGN DRUG AND DEVICE MANUFACTURERS.

(a) REGISTRATION OF CERTAIN FOREIGN ESTABLISHMENTS.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended by adding at the end the following:

''(5) The requirements of paragraphs (1) and (2) shall apply regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.''.

(b) UPDATING REGULATIONS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall update regula-

tions, as appropriate, to implement the amendment made by subsection (a).

SEC. 512. EXTENDING EXPIRATION DATES FOR CERTAIN DRUGS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance, or revise existing guidance, to address recommendations for sponsors of applications submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) regarding—

(1) the submission of stability testing data in such applications, including considerations for data requirements that could be streamlined or reduced to facilitate faster review of longer proposed expiration dates;

(2) establishing in the labeling of drugs the longest feasible expiration date scientifically supported by such data, taking into consideration how extended expiration dates may—

(A) help prevent or mitigate drug shortages; and

(B) affect product quality; and

(3) the use of innovative approaches for drug and combination product stability modeling to support initial product expiration dates and expiration date extensions.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, and again 2 years thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(1) the number of drugs for which the Secretary has requested the manufacturer make a labeling change regarding the expiration date; and

(2) for each drug for which the Secretary has requested a labeling change with respect to the expiration date, information regarding the circumstances of such request, including—

(A) the name and dose of such drug;

(B) the rationale for the request;

(C) whether the drug, at the time of the request, was listed on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), or was at risk of shortage;

(D) whether the request was made during a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(E) whether the manufacturer made the requested change by the requested date, and for instances where the manufacturer does not make the requested change, the manufacturer's justification for not making the change, if the manufacturer agrees to provide such justification for inclusion in the report.

SEC. 513. UNANNOUNCED FOREIGN FACILITY INSPECTIONS PILOT PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a pilot program under which the Secretary increases the conduct of unannounced inspections of foreign human drug facilities and evaluates the differences between inspections of domestic and foreign human drug facilities, including the impact of announcing inspections to persons who own or operate foreign human drug facilities in advance of an inspection. Such pilot program shall evaluate—

(1) differences in the number and type of violations of section 501(a)(2)(B) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) identified during unannounced and announced inspections of foreign human drug facilities and any other significant differences between each type of inspection;

(2) costs and benefits associated with conducting announced and unannounced inspections of foreign human drug facilities;

(3) barriers to conducting unannounced inspections of foreign human drug facilities and any challenges to achieving parity between domestic and foreign human drug facility inspections; and

(4) approaches for mitigating any negative effects of conducting announced inspections of foreign human drug facilities.

(b) PILOT PROGRAM INITIATION.—The Secretary shall initiate the pilot program under this section not later than 180 days after the date of enactment of this Act.

(c) REPORT.—The Secretary shall, not later than 180 days following the completion of the pilot program, make available on the website of the Food and Drug Administration a final report on the pilot program under this section, including—

(1) findings and any associated recommendations with respect to the evaluation under subsection

(a), including any recommendations to address identified barriers to conducting unannounced inspections of foreign human drug facilities;

(2) findings and any associated recommendations regarding how the Secretary may achieve parity between domestic and foreign human drug inspections; and

(3) the number of unannounced inspections during the pilot that would not be unannounced under existing practices.

SEC. 514. COMBATING COUNTERFEIT DEVICES.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(fff)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any device or container, packaging, or la-

beling thereof so as to render such device a counterfeit device.

''(3) The doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.''.

(b) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) in subsection (b)(8), by inserting '', or who violates section 301(fff)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device,'' after ''a counterfeit drug''; and

(2) in subsection (c), by inserting ''; or (6) for having violated section 301(fff)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a device being a counterfeit device, or for having violated section 301(fff)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the device was a counterfeit device'' before the period.

(c) SEIZURE.—Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended—

(1) by striking ", and (E)" and inserting ", (E)"; and

(2) by inserting ", (F) Any device that is a counterfeit device, (G) Any container, packaging, or labeling of a counterfeit device, and (H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit device or devices" before the period.

SEC. 515. STRENGTHENING MEDICAL DEVICE SUPPLY CHAINS.

(a) IN GENERAL.—Section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is amended—

(1) by redesignating subsections (h) and (i) as subsections (j) and (k), respectively; and

(2) by inserting after subsection (g) the following:

"(h) RISK MANAGEMENT PLANS.—Each manufacturer of a device that is critical to public health, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care, shall develop, maintain, and, as appropriate, implement a redundancy risk management plan that identifies and evaluates risks to the supply of the device, as applicable, for each estab-

lishment in which such device is manufactured. A risk management plan under this subsection—

''(1) may identify and evaluate risks to the supply of more than one device, or device category, manufactured at the same establishment; and

''(2) shall be subject to inspection and copying by the Secretary pursuant to section 704 or at the request of the Secretary.''.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, and annually for 4 years thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of information manufacturers submit pursuant to section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j) and applicable guidance issued with respect to such section.

SEC. 516. PREVENTING MEDICAL DEVICE SHORTAGES.

(a) NOTIFICATIONS.—Section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as amended by section 515, is further amended—

(1) in the flush text at the end of subsection (a), by inserting ''or of any other circumstance that is likely to lead to a meaningful disruption in the

supply of the device or a shortage of the device, and there is no other available device that could reasonably be substituted for that device in the United States'' before the period;

(2) in subsection (f), by inserting ''or (i)'' after ''subsection (a)''; and

(3) by inserting after subsection (h), as added by section 515, the following:

''(i) ADDITIONAL NOTIFICATIONS.—The Secretary may receive notifications from a manufacturers of a device that is life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or any other device the Secretary determines to be critical to the public health, pertaining to a permanent discontinuance in the manufacture of the device (except for any discontinuance as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption.''.

(b) GUIDANCE ON VOLUNTARY NOTIFICATIONS OF DISCONTINUANCE OR INTERRUPTION OF DEVICE MANUFACTURE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue draft guidance to facilitate voluntary notifications under subsection (i) of

section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as added by subsection (a). Such guidance shall include a description of circumstances in which a voluntary notification under such subsection (i) may be appropriate, recommended timeframes within which sponsors should submit such a notification, the process for receiving such notifications, and actions the Secretary may take to mitigate or prevent a shortage resulting from a discontinuance or interruption in the manufacture of a device for which such notification is received. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

SEC. 517. REMOTE RECORDS ASSESSMENTS FOR MEDICAL DEVICES.

(a) FACTORY INSPECTION.—Section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)(A)) is amended—

(1) in the first sentence, by inserting ''or device'' after ''processing of a drug''; and

(2) in the second sentence, by striking ''shall include'' and all that follows through the period at the end and inserting the following: ''shall include—

''(A) a description of the records requested; and

"(B) a rationale for requesting such information in advance of, or in lieu of, an inspection.".

(b) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue draft guidance describing circumstances in which the Secretary intends to issue requests for records or other information in advance of, or in lieu of, an inspection, processes for responding to such requests electronically or in physical form, and factors the Secretary intends to consider in evaluating whether such records are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

SEC. 518. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 506, is further amended by inserting after section 506K the following:

"SEC. 506L. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall initiate a pilot program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

''(b) DESIGNATION PROCESS.—The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially—

''(1) enhance drug quality; or

''(2) improve the manufacturing process for a drug and maintain drug quality, including by—

''(A) reducing development time for a drug using the designated manufacturing method; or

''(B) increasing or maintaining the supply of—

''(i) a drug that is life-supporting, life-sustaining, or of critical importance to providing health care; or

''(ii) a drug that is on the drug shortage list under section 506E.

''(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

''(1) SUBMISSION.—A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of such data or information by—

''(A) providing timely advice to, and interactive communication with, such person regarding the development of the method of manufacturing; and

''(B) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

''(2) EVALUATION AND DESIGNATION.—Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate such method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

''(d) REVIEW OF ADVANCED MANUFACTURING TECHNOLOGIES.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

''(1) expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology; and

''(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, to reference or rely upon, in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including a supplemental application, data and information about the des-

ignated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

''(e) IMPLEMENTATION AND EVALUATION OF ADVANCED MANUFACTURING TECHNOLOGIES PILOT.—

''(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after the date of enactment of this section, to discuss, and obtain input and recommendations from relevant stakeholders regarding—

''(A) the goals and scope of the pilot program, and a suitable framework, procedures, and requirements for such program; and

''(B) ways in which the Food and Drug Administration will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

''(2) PILOT PROGRAM GUIDANCE.—

''(A) IN GENERAL.—The Secretary shall—

''(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the pilot program under this section; and

"(ii) not later than 2 years after the date of enactment of this section, issue final guidance regarding the implementation of such program.

"(B) CONTENT.—The guidance described in subparagraph (A) shall address—

"(i) the process by which a person may request a designation under subsection (b);

"(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;

"(iii) the process to expedite the development and review of applications under subsection (d); and

"(iv) the criteria described in subsection (b) for eligibility for such a designation.

"(3) REPORT.—Not later than 3 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and submit to the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description and evaluation of the pilot program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. Such report shall include the following:

''(A) The number of persons that have requested designations and that have been granted designations.

''(B) The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.

''(C) The average number of calendar days for completion of evaluations under subsection (c)(2).

''(D) An analysis of the factors in data submissions that result in determinations to designate and not to designate after evaluation under subsection (c)(2).

''(E) The number of applications received under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, that have included an ad-

vanced manufacturing technology designated under this section, and the number of such applications approved.

''(f) SUNSET.—The Secretary—

''(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2029; and

''(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (d) prior to such date, if the Secretary determines such activities are in the interest of the public health.''.

SEC. 519. TECHNICAL CORRECTIONS.

(a) TECHNICAL CORRECTIONS TO THE CARES ACT.—Division A of the CARES Act (Public Law 116–136) is amended—

(1) in section 3111(1), by striking ''in paragraph (1)'' and inserting ''in the matter preceding paragraph (1)'';

(2) in section 3112(d)(1), by striking ''and subparagraphs (A) and (B)'' and inserting ''as subparagraphs (A) and (B)''; and

(3) in section 3112(e), by striking ''Federal Food, Drug, Cosmetic Act'' and inserting ''Federal Food, Drug, and Cosmetic Act''.

(b) TECHNICAL CORRECTIONS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT RELATED TO THE CARES ACT.—

(1) SECTION 506C.—Section 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)) is amended, in the flush text at the end, by striking the second comma after ''in the United States''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in section 3112 of division A of the CARES Act (Public Law 116–136).

(c) OTHER TECHNICAL CORRECTION TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 505B(f)(6)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(f)(6)(I)) is amended by striking ''subsection (a)(3)(B)'' and inserting ''subsection (a)(4)(C)''.

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