118TH CONGRESS  
1ST Session  

S.  

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

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,
3
4 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
5 (a) Short Title.—This Act may be cited as the “Pandemic and All-Hazards Preparedness and Response Act”.
6 (b) Table of Contents.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

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

TITLE II—FEDERAL PLANNING AND COORDINATION

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

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

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

TITLE IV—STRENGTHENING BIOSECURITY

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

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

TITLE VI—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

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

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

SEC. 101. TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.

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

(1) in paragraph (1), by striking “such Governor or tribal organization’s designee” and inserting “the designee of the Governor or Tribal organization, or the State or Tribal health official”;

(2) in paragraph (2)(B)—

(A) in the matter preceding clause (i), by striking “tribal organization” and inserting...
“Tribal organization, or the State or Tribal health official”; and

(B) in clause (v), by striking “tribal organization” and inserting “Tribal organization or State or Tribal health official”;

(3) in paragraph (6)—

(A) in the matter preceding subparagraph (A)—

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

(ii) by striking “appropriate committees of the Congress” and inserting “Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives”; and

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

(4) in paragraph (7)(A), by striking “tribal organization” and inserting “Tribal organization”; and

(5) in paragraph (8), by striking “2023” and inserting “2028”. 
SEC. 102. PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAM.

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

(1) in subsection (b)(2)—

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

and

(B) in subparagraph (H), by inserting “, such as community-based organizations, including faith-based organizations, and other public and private entities” after “stakeholders”;

(2) in subsection (g)—

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

(B) in paragraph (2)—

(i) in the paragraph heading, by striking “INFLUENZA” and inserting “RESPONSE”; and

(ii) in subparagraph (A)—

(I) by striking “to pandemic influenza” and inserting “to a pathogen
causing a pandemic, including pandemic influenza”; and

(II) by striking “such pandemic influenza” and inserting “such pandemic response”;

(C) in paragraph (5)—

(i) in the paragraph heading, by striking “INFLUENZA” and inserting “PANDEMIC RESPONSE”;

(ii) in the matter preceding subparagraph (A), by striking “2019” and inserting “2025”;

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

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

(D) in paragraph (6)—

(i) in subparagraph (A), in the matter preceding clause (i), by striking “The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in this section of section 319C–2” and inserting “The Secretary shall withhold from an en-
entity pursuant to paragraph (5) for non-compliance with the requirements of this section or section 319C–2 as follows”; and

(ii) in subparagraph (B), by inserting “with respect to the requirements of this section or section 319C–2” after “paragraph (5)”;

(3) in subsection (h)—

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

(B) in paragraph (4)—

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

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

(C) in paragraph (5)(A), by striking “For fiscal year 2007, the Secretary” and inserting “The Secretary”.
SEC. 103. IMPROVING AND ENHANCING PARTICIPATION OF EMS ORGANIZATIONS IN THE HOSPITAL PREPAREDNESS PROGRAM.

(a) Increasing Participation by EMS in the Hospital Preparedness Program.—Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended—

(1) in subsection (b)(1)(A)—

(A) in clause (iii)(III), by striking ‘‘; and’’ and inserting semicolon; and

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

‘‘(iv) one or more emergency medical service organizations; and

‘‘(v) to the extent practicable, one or more emergency management organizations; and’’; and

(2) in subsection (g)(1)—

(A) by striking the heading and inserting:

‘‘(1) Local Response Capabilities.—

‘‘(A) Program Coordination.—’’;

(B) by striking ‘‘extent practicable, ensure’’ and inserting the following: ‘‘extent practicable—

‘‘(i) ensure’’;
(C) by striking the period and inserting “;
and”; and

(D) by adding at the end the following:
“(ii) seek to increase participation of
eligible entities described in subsection
(b)(1)(A) with lower participation rates
relative to coalitions of other eligible enti-
ties, such as coalitions that include emer-
gency medical services organizations and
health care facilities in underserved
areas.”.

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

SEC. 104. IMPROVING MEDICAL READINESS AND RESPONSE
CAPABILITIES.

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

(1) in subsection (b)(2)—

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

(B) in subparagraph (B), by striking the
period and inserting “; and”; and
10

(C) by inserting at the end the following:

“(C) designate a lead entity to administer such award and support coordination between entities described in this subsection.”;

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

“(B) REGIONAL OPERATIONS.—An eligible entity shall establish and maintain, or leverage an existing, capability to enable coordination of regional medical operations, which may include systems to facilitate information sharing and coordination, within a coalition described under subsection (b)(1)(A) and, as appropriate, between multiple coalitions that are in close geographic proximity to each other.”; and

(3) in subsection (j)(1)—

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

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

SEC. 105. PILOT PROGRAM TO SUPPORT STATE MEDICAL STOCKPILES.

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

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

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

(2) in paragraph (4)—

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

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

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

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

(D) in subparagraph (I), as so redesignated, by striking “State efforts” and inserting “State or regional efforts”; and

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

(4) by inserting after paragraph (4) the following:
“(5) COORDINATION.—An entity in receipt of an award under paragraph (1), in carrying out the activities under this subsection, shall coordinate with appropriate health care entities, health officials, and emergency management officials within the jurisdiction of such State or States.”; and

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

(b) GAO REPORT.—Section 2409(b) of the PREVENT Pandemics Act (Public Law 117–328) is amended—

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

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

(3) by adding at the end the following:

“(4) the impact of any regional stockpiling approaches carried out under such subsection (i)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).”.
SEC. 106. ENHANCING DOMESTIC WASTEWATER SURVEILLANCE FOR PATHOGEN DETECTION.

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

“SEC. 2827. WASTEWATER SURVEILLANCE FOR PATHOGEN DETECTION.

“(a) WASTEWATER SURVEILLANCE SYSTEM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other Federal departments and agencies, shall award grants, contracts, or cooperative agreements to eligible entities to establish, maintain, or improve activities related to the detection and monitoring of infectious diseases through wastewater for public health emergency preparedness and response purposes.

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

“(1) be a State, Tribal, or local health department, or a partnership between such a health department and other public and private entities; and

“(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include—
“(A) a description of activities proposed to be carried out pursuant to an award under subsection (a);

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

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

“(D) a plan to sustain such wastewater surveillance activities described in such application following the conclusion of the award period; and

“(E) any additional information the Secretary may require.

“(c) CONSIDERATION.—In making awards under subsection (a), the Secretary may give priority to eligible entities that have submitted an application that—

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

“(2) provides an assessment of community needs related to ongoing infectious disease moni-
toring, including burden of infectious diseases that can be detected in wastewater and availability of other forms of infectious disease surveillance.

“(d) USE OF FUNDS.—An eligible entity shall, as appropriate, use amounts awarded under this section to—

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

“(2) conduct wastewater surveillance, as appropriate, at individual facilities, institutions, and locations in rural areas, in which there is an increased risk of infectious disease outbreaks, or areas in which wastewater is not treated through the relevant local utility of the jurisdiction; and

“(3) implement projects that use evidence-based or promising practices to conduct wastewater surveillance activities.

“(e) PARTNERSHIPS.—In carrying out activities under this section, eligible entities shall identify opportunities to partner with other public or private entities to leverage relevant capabilities maintained by such entities, as appropriate and consistent with this section.

“(f) TECHNICAL ASSISTANCE.—The Secretary, in consultation with the heads of other applicable Federal agencies and departments, as appropriate, shall provide
technical assistance to recipients of awards under this section to facilitate the planning, development, and implementation of activities described in subsection (d).

“(g) Authorization of Appropriations.—To carry out this section, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2024 through 2028.’’.

(b) Wastewater Surveillance Research.—

(1) In general.—The Secretary of Health and Human Services (in this subsection referred to as the ‘‘Secretary’’) shall continue to conduct or support research on the use of wastewater surveillance to detect and monitor emerging infectious diseases, which may include—

(A) research to improve the efficiency of wastewater sample collection and analysis and increase the sensitivity and specificity of wastewater testing methods; and

(B) implementation and development of evidence-based practices to facilitate the estimation of population-level data within a community.

(2) Non-duplication of effort.—The Secretary shall ensure that activities carried out under this subsection do not unnecessarily duplicate efforts
of other agencies and offices within the Department of Health and Human Services related to wastewater surveillance.

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

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

(1) in subsection (a)(3)(A), by striking “subsection (b)(3)’’ and inserting “subsection (b)(4)’’;

(2) in subsection (b)—

(A) by redesignating paragraphs (3) through (6) as paragraphs (4) through (7), respectively; and

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

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

(3) by amending subsection (d) to read as follows:

“(d) USES OF FUNDS.—Amounts appropriated under subsection (f) may be used by the Secretary to provide training and technical assistance with respect to the planning, development, and operation of assessments and
plans under subsection (a) and control programs under
subsection (b). The Secretary may provide such training
and technical assistance directly or through awards of
grants or contracts to public and private entities.”; and

(4) in subsection (f)(1), by striking “2019
through 2023” and inserting “2024 through 2028”.

TITLE II—FEDERAL PLANNING
AND COORDINATION

SEC. 201. ALL-HAZARDS EMERGENCY PREPAREDNESS AND
RESPONSE.

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

(1) in subsection (b)—

(A) in paragraph (3)—

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

“(A) IN GENERAL.—Oversee advanced”;

and

(ii) by adding at the end following:

“(B) DEVELOPMENT OF REQUIRE-
MENTS.—Lead the development and approval,
and, on a routine basis, the review and update,
of requirements for such countermeasures and
products, including related capabilities, to in-
form the advanced research, development, pro-
curement, and replenishment decisions of the
Department of Health and Human Services.”;

(B) in paragraph (4)—

(i) in subparagraph (F)—

(I) in the matter preceding clause
(ii), by striking “and in consultation
with the Secretary of Homeland Secu-

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

(ii) in subparagraph (G)—

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

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

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

(IV) by adding at the end the fol-

“(iv) that include, as appropriate, par-

participation by relevant industry, academia,
professional societies, and other stakeholders.”;

(iii) in subparagraph (H)—

(I) by inserting “and the Director of the Office of Pandemic Preparedness and Response” after “Security Affairs”; and

(II) by inserting “and medical product and supply capacity planning pursuant to subparagraph (J), including discussion of any relevant identified supply chain vulnerabilities” before the period at the end;

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

(v) in subparagraph (J)(i), in the matter preceding subclause (I), by inserting “(including ancillary medical supplies and components of medical products, such as active pharmaceutical ingredients, key starting materials, and medical device components)” after “supply needs”; and

(C) in paragraph (7)—
(i) in the matter preceding subpara-
graph (A), by inserting “and the require-
ments developed pursuant to paragraph
(3)(B)” after “subsection (d)”;

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

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

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

(2) in subsection (d)—

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

“(1) IN GENERAL.—Not later than March 15,
2020, and biennially thereafter, the Assistant Sec-
retary for Preparedness and Response shall develop
and submit to the Committee on Health, Education,
Labor, and Pensions of the Senate and the Com-
mittee on Energy and Commerce of the House of
Representatives a coordinated strategy for medical
countermeasures to address chemical, biological, radiological, and nuclear threats, informed by the requirements developed pursuant to subsection (b)(3)(B). Not later than 180 days after the submission of such strategy to such committees, the Assistant Secretary for Preparedness and Response shall submit an accompanying implementation plan to such committees. In developing such a strategy and plan, the Assistant Secretary for Preparedness and Response shall consult with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1.”; and

(B) in paragraph (2), in the matter preceding subparagraph (A), by inserting “strategy and” before “plan”; and

(3) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting “, including an emerging infectious disease,” after “any such agent”; and

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

SEC. 202. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 of the Public Health Service Act is amended—

(1) in subsection (a)(3)—

(A) by striking “In 2022, the” and inserting “The”; and

(B) by inserting “, maintaining, and sustaining” after “establishing”; and

(2) in subsection (b)—

(A) in paragraph (2)—

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

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

(B) in paragraph (3)—

(i) in subparagraph (C), by inserting “and current capacity of facilities within such systems, as applicable” before the period;

(ii) in subparagraph (D), by inserting “and other medical products and medical supplies directly related to responding to chemical, biological, radiological, or nuclear threats, including emerging infectious dis-
cases, and incidents covered by the National Response Framework, as applicable and consistent with the activities carried out under section 2811(b)(4)(J)” before the period; and

(iii) by adding at the end the following:

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

(C) in paragraph (5), by inserting “applicable federally-funded activities and” after “(including”;

(D) in paragraph (8)—

(i) in subparagraph (A), by inserting “public health and medical” before “activities”; and

(ii) in subparagraph (B), by striking “familiarity with” and inserting “understanding of, and coordination between,”;

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

(F) by inserting after paragraph (8) the following:
“(9) OTHER SETTINGS.—Supporting Federal, State, local, and Tribal coordination and planning with respect to facilities in which there is an increased risk of infectious disease outbreaks, including such facilities that address the needs of at-risk individuals, in the event of a public health emergency declared under section 319.”;

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

“(11) OTHER HAZARDS.—Assessing current and potential health security threats from natural disasters or other extreme weather events with respect to public health and medical preparedness and response.”; and

(H) by striking “tribal” each place it appears and inserting “Tribal”.

SEC. 203. IMPROVING DEVELOPMENT AND DISTRIBUTION OF DIAGNOSTIC TESTS.

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

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

“(a) FRAMEWORK.—The Secretary shall develop, make publicly available not later than 1 year after the date of enactment of the Pandemic and All-Hazards Prepared-
ness and Response Act, and update not less frequently than every 3 years thereafter, a strategic framework for the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, and for rapid scaling of testing capacity, in response to chemical, biological, radiological, or nuclear threats, including infectious diseases for which a public health emergency is declared under section 319, or that has significant potential to cause such a public health emergency. Such strategic framework shall take into consideration—

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

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

“(3) medical supply needs related to testing, including diagnostic testing, equipment, supplies, and component parts, and any potential vulnerabilities
related to the availability of such medical supplies
and related planning, consistent with section
2811(b)(4)(J);

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

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

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

“(c) CAPACITY BUILDING.—The Secretary may con-
tract with public and private entities, as appropriate, to
increase domestic capacity in the rapid development, vali-
dation, authorization, manufacture, procurement, and dis-
tribution of diagnostic tests, as appropriate, to State,
local, and Tribal health departments and other appro-
perate entities for immediate public health response activi-
ties to address an 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.”.

SEC. 204. PILOT PROGRAM FOR PUBLIC HEALTH DATA AVAILABILITY.

(a) Situational Awareness System.—Section 319D of the Public Health Service Act (42 U.S.C. 247d-4) is amended—

(1) in subsection (c)—

(A) in paragraph (1), by inserting “, and facilitate the leveraging of relevant public health data across the Department of Health and Human Services” after “extent practicable”; and

(B) in paragraph (2)—

(i) in subparagraph (A)—

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

(II) by inserting “the sharing of information from applicable public health data systems,” after “Technology),”; and

(III) by striking “; and” at the end and inserting a semicolon;
(ii) in subparagraph (B), by striking
the period at the end and inserting “;
and”; and

(iii) by adding at the end the follow-
ing:
“(C) facilitate communication, including
bidirectional communication or other means of
communication, to enable timely information
sharing with State, local, and Tribal public
health officials, between agencies and offices of
the Department of Health and Human Services,
and with health care providers, as applicable
and appropriate.”;

(2) in subsection (d)—

(A) in paragraph (1)—

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

(ii) by striking “, in collaboration with
appropriate” and inserting “. Such States
or consortia of States shall carry out such
activities in collaboration with appropriate
stakeholders, such as health information exchanges, laboratory information systems,”;

(B) in paragraph (2)(A), by inserting “pursuant to paragraph (3)” after “may require”; 

(C) by striking paragraph (6); 

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

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

“(3) DATA PLAN.—For purposes of this subsection, the Secretary shall develop a plan for data elements to be reported to the Secretary pertaining to potentially catastrophic infectious disease outbreaks, in such form and manner and at such timing and frequency as determined by the Secretary. When developing the plan under this subsection, the Secretary shall—

“(A) align with the standards and implementation specifications adopted by the Secretary under section 3004, where applicable, and update, as necessary and consistent with applicable requirements of subsection (b)(3)
and section 2823, uniform standards for applicable entities to report data elements;

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

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

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

(i) in subparagraph (A), by striking “emergencies;” and inserting “emergencies, including such diseases recommended by the National Public Health Data Board established under section 319D–2; and”;

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

(iii) by striking subparagraph (C); and

(3) in subsection (h)—

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

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

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

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

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

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

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

“(1) **IN GENERAL.**—The Secretary shall establish a National Public Health Data Board to advise, and make recommendations to the Secretary with respect to potentially catastrophic infectious diseases appropriate for inclusion in the public health situational awareness system pilot program established pursuant to section 319D(d) and the website established under subsection (a)(1).
“(2) MEMBERSHIP.—The Board established under paragraph (1) shall consist of the following members:

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

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

“(ii) The Secretary of Defense.

“(iii) The Secretary of Veterans Affairs.

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

“(v) The Director of the National Institutes of Health.

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

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

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


“(x) The Commissioner of Food and Drugs.
“(xi) Such other heads of departments, agencies, and offices as the Secretary determines appropriate.

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

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

“(I) individuals with expertise or experience in—

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

or

“(bb) health data standards and technology systems, which may include hospital, pharmacy, laboratory information systems and health information exchanges;

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

“(ii) individuals with such other specific expertise as the Secretary determines appropriate.

“(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter existing obligations under
regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and this section shall be applied in a manner that is consistent with applicable Federal and State privacy law, at a minimum.

“(d) NONDUPICATION OF EFFORTS.—The Secretary shall ensure that the activities carried out by the Board under this section do not duplicate the efforts of other Federal advisory committees that advise and make recommendations to the Secretary.

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

SEC. 205. COMBATING ANTIMICROBIAL RESISTANCE.

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

(1) in subsection (a)—

(A) in paragraph (1), by inserting “and activities” after “Federal programs”;

(B) in paragraph (2)—

(i) by striking “public health constituencies, manufacturers, veterinary and medical professional societies and others” and inserting “the Advisory Council described in subsection (b) and relevant public and private entities”; and
(ii) by inserting “, pursuant to para-
graph (4),” after “comprehensive plan”;

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

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

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

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

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

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

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

(D) by redesignating paragraph (4) as
paragraph (5);
(E) by inserting after paragraph (3) the following:

“(4) ACTION PLAN.—Not later than October 1, 2025, and every 5 years thereafter, the task force described in paragraph (1) 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 a plan regarding Federal programs and activities to combat antimicrobial resistance, including measurable outcomes, as appropriate, informed by the agenda described in paragraph (3) and input provided by the Advisory Council described in subsection (b) and other relevant stakeholders provided pursuant to paragraph (2).”;

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

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

“(b) ADVISORY COUNCIL.—

“(1) IN GENERAL.—The Secretary may continue the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, referred to in this subsection as the ‘Advisory Council’.
“(2) Duties.—The Advisory Council shall advise and provide information and recommendations to the Secretary, acting through the Task Force established under subsection (a), regarding Federal programs and activities intended to reduce or combat antimicrobial-resistant bacteria or fungi that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving Federal efforts related to factors described in subsection (a)(3) and other topics related to antimicrobial resistance, as appropriate.

“(3) Meetings and Coordination.—

“(A) Meetings.—The Advisory Council shall meet not less than biannually and, to the extent practicable, in coordination with meetings of the task force established under subsection (a).

“(B) Coordination.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the task force established under subsection (a).
“(4) FACA.—Chapter 10 of title 5, United States Code, shall apply to the activities and duties of the Advisory Council.”; and

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

SEC. 206. STRATEGIC NATIONAL STOCKPILE AND MATERIAL THREATS.

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

(1) in subsection (a)—

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

“(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including—

“(aa) whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats; and

“(bb) in the case of a countermeasure that addresses a biological agent, whether such agent
has an increased likelihood to become resistant to, more resistant to, or evade, such countermeasure relative to other available medical countermeasures;”;

and

(B) in paragraph (3)—

(i) in subparagraph (B), by striking “are followed, regularly reviewed, and updated with respect to such stockpile” and inserting “with respect to such stockpile are followed, regularly reviewed, and updated to reflect best practices”; 

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

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

“(H) utilize tools to enable the timely and accurate tracking, including the location and geographic distribution and utilization, of the contents of the stockpile throughout the deployment of such contents;”;

(2) in subsection (c)(2)(C)—

(A) by striking “promptly”; and
SEC. 207. MEDICAL COUNTERMEASURES FOR VIRAL THREATS WITH PANDEMIC POTENTIAL.

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

(1) in subsection (c)(4)—

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

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

“(I) rapid diagnostics;

“(II) broad spectrum antimicrobials;

“(III) medical countermeasures for virus families that have significant potential to cause a pandemic, including such countermeasures that take
either pathogen-specific or broad spectrum approaches; and

“(IV) technologies to improve the production and use of medical countermeasures, which may include vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures.”; and

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

“(ii) threats that—

“(I)(aa) consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza; or

“(bb) include priority virus families and other viral pathogens with a significant potential to cause a pandemic; and

“(II) may include the advanced research and development, manufac-
turing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material);’’;

(2) in subsection (d)(2), by striking “$611,700,000 for each of fiscal years 2019 through 2023” and inserting “$950,000,000 for each of fiscal years 2024 through 2028”; and

(3) in subsection (e)(1), by amending subparagraph (D) to read as follows:

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

SEC. 208. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

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

(1) in paragraph (1)—
(A) by redesignating subparagraph (D) as subparagraph (E); and

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

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

(2) in paragraph (2), by striking “, as appropriate”; and

(3) by adding at the end the following:

“(3) INFORMATION SHARING.—The Secretary shall, as appropriate and in a manner that does not compromise national security, share information related to recommendations made and strategies developed under subparagraphs (A) and (C) of paragraph (1) with relevant stakeholders, including industry and State, local, and Tribal public health departments.”.
SEC. 209. STRENGTHENING PUBLIC HEALTH COMMUNICATION.

(a) Public Health Communications Advisory Committee.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish an advisory committee to be known as the Public Health Communications Advisory Committee (referred to in this subsection as the “Advisory Committee”).

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

   (1) critical aspects of communication and dissemination of scientific and evidence-based public health information during public health emergencies;

   (2) research from relevant external stakeholders related to evidence-based or evidence-informed strategies and best practices to effectively communicate and disseminate such information; and

   (3) strategies to improve communication and dissemination of scientific and evidence-based public health information to the public and to improve communication between Federal, State, local, and Tribal health officials.

(c) Composition.—The Advisory Committee shall be composed of—
(1) appropriate Federal officials, appointed by
the Secretary, who shall serve as nonvoting mem-
bers; and

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

(A) expertise in public health, including in-
dividuals with experience in State, local, and
Tribal health departments, medicine, commu-
ications, related technology, psychology, men-
tal health and substance use disorders, national
security;

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

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

(d) DISSEMINATION.—The Secretary shall review the
recommendations of the Advisory Committee and, not
later than 180 days after receipt of the report under sub-
section (b), 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 this section.
(c) TERMINATION.—The Advisory Committee shall terminate 2 years after the date of enactment of this Act.

SEC. 210. FELLOWSHIP AND TRAINING PROGRAMS.

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

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

“(a) IN GENERAL.—The Secretary,”; and

(2) by adding at the end the following:

“(b) NONCOMPETITIVE CONVERSION.—

“(1) IN GENERAL.—The Secretary may non-competitively convert an individual who has completed an epidemiology, surveillance, or laboratory fellowship or training program under subsection (a) to a career-conditional appointment without regard to the provisions of subchapter I of chapter 33 of title 5, United States Code, provided that individual meets qualification requirements for the appointment.”.

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

(a) GAO STUDY.—The Comptroller General of the United States shall conduct a study on the economic impact and health outcomes associated with the response to the COVID–19 pandemic in the United States. Such study shall include—
(1) a summary of strategies used by local governmental entities, States, and the Federal Government to contain and mitigate the spread of COVID–19 during the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, including—

(A) limitations on large gatherings of people;
(B) the closure of schools, businesses, houses of worship, and other facilities;
(C) masking policies;
(D) testing policies; and
(E) vaccination policies;

(2) an analysis and review of the scientific evidence related to the effectiveness of such strategies in preventing or mitigating the spread of COVID–19, including estimates of the burden of disease and death that were avoided through such interventions;

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

(4) an accounting of Federal funding used to implement such strategies.
(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. Such report shall include recommendations based on the findings of the study conducted under subsection (a) regarding the impact of such strategies during the COVID–19 public health emergency, including how to improve future responses.

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

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

(a) Treatment of Certain Ineligible Requests Related to COVID–19 Countermeasures.—

(1) Requests initially submitted under CICP.—

(A) In general.—In the case of a request for compensation submitted under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) for an injury or death related to a COVID–19 vaccine that the Secretary determines to be ineligible pursuant to subpara-
graph (B) of such section 319F–4(b)(4), as added by subsection (b)(1), the Secretary shall, not later than 30 days after such determination, notify the individual submitting the request of such determination.

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

(i) 1 year after receiving such notification under subparagraph (A); or

(ii) the last date on which the individual otherwise would be eligible to submit a petition relating to such injury, as specified in section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16).

(C) ELIGIBILITY.—To be eligible to submit a petition in accordance with subparagraph (B),
the petitioner shall have submitted the request for compensation under section 319F–4 of the Public Health Service Act that was determined to be ineligible not later than the deadline for filing a petition under section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) that applies with respect to the administration of such vaccine.

(2) Requests initially submitted under VICP.—

(A) In general.—If a special master determines that—

(i) a petition submitted under section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) related to a COVID–19 vaccine is ineligible for the National Vaccine Injury Compensation Program under subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa–10 et seq.) because it relates to a vaccine administered at a time when the vaccine was not included in the Vaccine Injury Table under section 2114 of such Act (42 U.S.C. 300aa–14); and
(ii) the vaccine was administered when it was a covered countermeasure subject to a declaration under section 319F–3(b) of such Act (42 U.S.C. 247d–6d(b)), the special master shall, not later than 30 days after such determination, notify the petitioner of such determination.

(B) Submission of request.—An individual who receives a notification described in subparagraph (A) shall be eligible to submit a request for compensation under section 319F–4(b) of the Public Health Service Act (42 U.S.C. 247d–6e) with respect to the same vaccine administration claimed in the petition submitted under section 2111 of such Act—

(i) not later than 1 year after receiving such notification; or

(ii) in the case that the notification is issued after judicial review of the petition under subsection (e) or (f) of section 2112 of such Act (42 U.S.C. 300aa–12), not later than 1 year after the decision of the United States Court of Federal Claim or the mandate is issued by the United States
Court of Appeals for the Federal Circuit
pursuant to such subsection (e) or (f).

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

(b) CHANGES TO CERTAIN PROGRAMS.—

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

(A) in subsection (b)(4)—

(i) by striking “Except as provided”
and inserting the following:
“(A) IN GENERAL.—Except as provided”; and

(ii) by adding at the end the fol-
lowing:
“(B) EXCLUSION OF INJURIES CAUSED BY
VACCINES ON THE VACCINE INJURY TABLE.—
Notwithstanding any other provision of this sec-
tion, no individual may be eligible for com-
pensation under this section with respect to a vaccine that, at the time it was administered, was included in the Vaccine Injury Table under section 2114.”; and

(B) in subsection (d)(3)—

(i) by striking “This section” and inserting the following:

“(A) IN GENERAL.—This section”; and

(ii) by adding at the end the following:

“(B) EXHAUSTION OF REMEDIES.—A covered individual shall not be considered to have exhausted remedies as described in paragraph (1), nor be eligible to seek remedy under section 319F–3(d), unless such individual has provided to the Secretary all supporting documentation necessary to facilitate the determinations required under subsection (b)(4).”.

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

(A) in section 2111(a)(2)(A) (42 U.S.C. 300aa–11(a)(2)(A)), in the matter preceding clause (i), by inserting “containing the informa-
tion required under subsection (c)” after “un-
less a petition”;

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

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

and

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

(C) in section 2114(e) (42 U.S.C. 300aa–
14(e))—

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

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

“(4) LICENSURE REQUIREMENT.—Notwith-
standing paragraphs (2) and (3), the Secretary may
not revise the Vaccine Injury Table to include a vac-
cine for which the Centers for Disease Control and
Prevention has issued a recommendation for routine use in children or pregnant women until at least one application for such vaccine has been approved under section 351. Upon such revision of the Vaccine Injury Table, all vaccines to prevent the same infectious disease, including vaccines authorized under emergency use pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, shall be considered included in the Vaccine Injury Table.”; and

(D) in section 2116 (42 U.S.C. 300aa–16), by adding at the end the following:

“(d) **Clarification.**—Notwithstanding subsections (a) and (b), an injury or death related to a vaccine administered at a time when the vaccine was a covered countermeasure subject to a declaration under section 319F–3(b) shall not be eligible for compensation under the Program.”.

**SEC. 302. ACCELERATING INJURY COMPENSATION PROGRAM ADMINISTRATION AND ENSURING PROGRAM INTEGRITY.**

(a) In General.—Section 2112(c) of the Public Health Service Act (42 U.S.C. 300aa12(c)) is amended—

(1) in paragraph (1), by striking “not more than 8 special masters” and inserting “not fewer than 10 special masters”; and
(2) in paragraph (4)—

(A) by striking “a term of 4 years” and inserting “an initial term of 4 years”;

(B) by striking the second and third sentences; and

(C) by adding at the end the following:

“An individual appointed as special master may be reappointed to serve one or more additional terms of up to 8 years each, pursuant to paragraph (1), and subject to termination under paragraphs (2) and (3).”.

(b) Petitions for Compensation.—Section 2111(a)(2)(A)(i) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

(1) in subclause (I), by striking “; and” and inserting a semicolon;

(2) in subclause (II)—

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

(B) by striking “; or” and inserting “; and”; and

(3) by adding at the end the following:

“(III) the judgment described in subclause (I) does not result from a petitioner’s motion to dismiss the case; or”.
(c) COMPENSATION.—Section 2115(e)(1) of the Public Health Service Act (42 U.S.C. 300aa–15(e)(1)) is amended by adding at the end the following: “When making a determination of good faith under this paragraph, the special master or court may consider whether the petitioner demonstrated an intention to obtain compensation on such petition and was not merely seeking to satisfy the exhaustion requirement under section 2121(b).”.

SEC. 303. COMPENSATION FOR INJURIES RELATING TO THE PUBLIC HEALTH EMERGENCY CAUSED BY SARS–COV–2.

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

(1) Notwithstanding the filing deadline applicable under section 319F–4, the claim shall be filed within 3 years of the administration or use of the covered countermeasure, or one year after enactment of this section, whichever is later, and, if a claim
filed under the Program with respect to such admin-
istration or use was filed before the date of enact-
ment of this Act and denied on the basis of having
not been filed within the time period required under
subsection (b)(4) of such section 319F–4, such claim
may be refiled pursuant to this paragraph.

(2) With respect to a claim relating to the ad-
ministration of a COVID–19 vaccine, such a claim
may be filed under the Program only if the adminis-
tration of such vaccine occurred prior to the addition
of the vaccine to the Vaccine Injury Table under sec-
tion 2114 of the Public Health Service Act (42

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

(b) PROFESSIONAL JUDGMENT BUDGET.—

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

(A) in consultation with the Attorney Gen-
eral, shall submit a budget outlining the re-
source needs for each agency for purposes of
carrying out the National Vaccine Injury Compensation Program under subtitle 2 of title XXI of such Act (42 U.S.C. 300aa–10 et seq.) for fiscal years 2024 through 2028; and

(B) shall submit a budget outlining resource needs for purposes of carrying out the Countermeasures Injury Compensation Program under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) for fiscal years 2024 through 2028.

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

(c) NASEM REPORT.—The Secretary of Health and Human Services shall seek to enter into a contract with the National Academies of Sciences, Engineering, and Medicine under which such National Academies shall report, not later than 3 years after the date of enactment of this Act, on the Countermeasure Injury Compensation Program under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e), including recommendations to improve the administration of such program and wheth-
er Congress should adjust the compensation payments available under such program.

SEC. 304. REVIEW OF REGULATIONS.

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

SEC. 305. SUPPORTING INDIVIDUALS WITH DISABILITIES, OLDER ADULTS, AND OTHER AT-RISK INDIVIDUALS DURING EMERGENCY RESPONSES.

(a) Technical Assistance Centers on At-risk Individuals and Disasters.—

(1) In general.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) may, through grants, contracts, or cooperative agreements to eligible entities, establish more than one research, training, and technical assistance centers to provide appropriate information, training, and technical assistance to States, localities, Tribes, and other applicable entities related to addressing the unique needs and considerations of at-risk individuals, as defined in section 2802(b)(4) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(4)), in the event of a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d).
(2) Responsibilities of the centers.—The centers established under paragraph (1) shall conduct activities for the purpose of—

(A) developing, identifying, evaluating, and disseminating evidence-based or evidence-informed strategies to improve health and other related outcomes for at-risk individuals related to public health emergencies, including by addressing such unique needs and considerations in carrying out public health and medical activities to prepare for, respond to, and recover from, such public health emergencies; and

(B) assisting applicable entities in the implementation of such evidence-based strategies, including through sub-grants, contracts, or cooperative agreements.

(3) Priority.—In awarding grants for activities described in this subsection, the Secretary shall give priority to eligible entities with demonstrated expertise in, and ability to carry out, the activities described in paragraph (2).

(4) Consultation.—In carrying out activities under paragraph (2), the centers established under paragraph (1) shall take into consideration relevant findings and recommendations of, and, as appro-
appropriate, consult with, the National Advisory Committee on Individuals with Disabilities and Disasters established under section 2811C of the Public Health Service Act (42 U.S.C. 300hh–10d), the National Advisory Committee on Children and Disasters under section 2811A of such Act (42 U.S.C. 300hh–10b), and the National Advisory Committee on Seniors and Disasters under section 2811B of such Act (42 U.S.C. 300hh–10c).

(5) Reports.—Not later than 2 years after the date of enactment of this Act and every 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 describing the activities carried out under this subsection during the preceding 2 fiscal years.

(6) Sunset.—This subsection shall cease to have force or effort on September 30, 2028.

(b) Crisis Standards of Care.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance to States and localities on the development or modification of State and local crisis standards
of care for use during the response to a public health
emergency declared by the governor of a State or by the
Secretary under section 319 of the Public Health Service
Act (42 U.S.C. 247d), or a major disaster or emergency
declared by the President under section 401 or 501, re-
respectively, of the Robert T. Stafford Disaster Relief and
Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-
sure that such standards of care are consistent with the
nondiscrimination requirements of section 504 of the Re-
habilitation Act of 1973 (29 U.S.C. 794), title II of the
Americans with Disabilities Act of 1990 (42 U.S.C. 12131
et seq.), and the Age Discrimination Act of 1975 (42
U.S.C. 6101 et seq.).

SEC. 306. NATIONAL ADVISORY COMMITTEES.

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

(1) in subsection (c)—

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

(B) by striking the period and inserting “; and

(C) by adding at the end the following:
“(2) recommendations to the Director of the Office of Pandemic Preparedness and Response Policy and to Congress with respect to the public health and emergency preparedness needs of children.”; and

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

(b) **National Advisory Committee on Seniors and Disasters**.—Section 2811B of the Public Health Service Act (42 U.S.C. 300hh–10c) is amended—

(1) in subsection (c)—

(A) by striking “may provide advice” and inserting the following: “may provide—

“(1) advice”;

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

(C) by adding at the end the following:

“(2) recommendations to the Director of the Office of Pandemic Preparedness and Response Policy and to Congress with respect to the public health and emergency preparedness needs of seniors.”;

(2) in subsection (d)—

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

(B) in paragraph (2)—
66

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

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

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

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

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

   and

   (3) by amending subsection (g) to read as follows:

   “(g) SUNSET.—The Advisory Committee shall terminate on September 30, 2028.”.

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

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

   (2) by inserting after subsection (b) the following:
“(c) ADDITIONAL DUTIES.—The Advisory Committee may provide—

“(1) advice and recommendations to the Secretary and to Congress with respect to individuals with disabilities and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this title and title III; and

“(2) recommendations to the Director of the Office of Pandemic Preparedness and Response Policy and to Congress with respect to the public health and emergency preparedness needs of individuals with disabilities.”;

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

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

(B) in paragraph (2)—

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

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

“(K) 15 non-Federal members (at least 4 of whom shall be individuals with disabilities) from diverse backgrounds, including the fol-
“(i) One representative from each of the following:

“(I) A nongovernmental organization that provides disaster preparedness and response services.

“(II) A community-based organization that represents individuals with multiple types of disabilities.

“(III) A State-based organization that represents individuals with multiple types of disabilities.

“(IV) A national organization that represents individuals with multiple types of disabilities.

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

“(VI) An organization that provides relevant housing services, including during the response to, and recovery from, disasters.

“(VII) An organization that represents disabled veterans.

“(ii) Four individuals with geographically diverse expertise in emergency management.
“(iii) Two non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery.”; and

(C) by adding at the end the following:

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

(4) by amending subsection (h), as so designated, to read as follows:

“(h) SUNSET.—The Advisory Committee shall terminate on September 30, 2028.”.

SEC. 307. RESEARCH AND COORDINATION OF ACTIVITIES CONCERNING THE 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) coordinate activities among relevant Federal departments and agencies with respect to addressing the long-term health effects of SARS-CoV-2 infec-
tion, which may include conditions that arise as a result of such infection;

(2) 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 re-infection, which may include conditions and any effects on development, cognition, and neural structure and function that arise as a result of such infection; and

(3) consistent with the findings of studies and research under paragraph (1), in consultation with health and public health professional associations, scientific and medical researchers, and other relevant experts, develop and inform recommendations, guidance, and educational materials on the long-term effects of SARS–CoV–2 infection, which may include conditions that arise as a result of such infection, and provide such recommendations, guidance, and educational materials to health care providers and the general public.

(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) ADDITIONAL ACTIVITIES.—The Secretary may—

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

(A) the improvement of health care delivery for individuals experiencing long-term
health effects of SARS–CoV–2, which may include conditions that arise as a result of such
infection;

(B) the identification of any trends associated with differences in diagnosis and treatment of the long-term health effects of SARS–CoV–2 infection and related conditions; and

(C) the development or identification of
tools and strategies to help health care entities
and providers care for such populations, which
may include addressing any differences identified pursuant to subparagraph (B);

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

(3) establish a primary care technical assistance
initiative to convene primary care providers and or-
ganizations, which may include support for con-
continuing training and education for such providers, as applicable and appropriate, in order to collect and disseminate best practices related to the care of individuals with long-term health effects of SARS–CoV–2 infection, which may include conditions that arise as a result of such infection.

(d) 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.

(e) Public Availability of Information.—In making information or reports publicly available under this section, the Secretary shall take into consideration the delivery of such information in a manner that takes into account the range of communication needs of the intended recipients, including at-risk individuals.
SEC. 308. NATIONAL ACADEMIES STUDY ON PRIZES.

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

(1) alternative models for directly funding, or stimulating investment in, biomedical research and development that delink research and development costs from the prices of drugs, including the progressive replacement of patents and regulatory exclusivities on new drugs with a combination of expanded support for research and innovation prizes to reward the successful development of drugs or achievement of related milestones;

(2) the dollar amount of innovation prizes for different stages of research and development of different classes or types of drugs, and total annual funding, that would be necessary to stimulate investment sufficient to achieve such successful drug development and related milestones;

(3) the relative effectiveness and efficiency of such alternative models in stimulating innovation, compared to the status quo that includes patents and regulatory exclusivities;
(4) strategies to implement such alternative models described in paragraph (1), including a phased transition over time;

(5) the anticipated economic and societal impacts of such alternative models, including an assessment of impact on—

(A) the number and variety of new drugs that would be developed, approved, and marketed in the United States, including such new drugs intended to prevent, diagnose, or treat a rare disease or condition;

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

(C) access to medication and health outcomes;

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

(E) the number of manufacturers that would be seeking approval for a drug or bringing a drug to market for the first time;

(F) Federal discretionary and mandatory spending; and

(G) public and private insurance markets.
(b) Authorization of Appropriations.—To carry out this section, there is authorized to be appropriated $3,000,000 for fiscal year 2024.

(c) Requirements.—In conducting the study pursuant to subsection (a), the National Academies shall hold not fewer than 2 public listening sessions to solicit feedback from interested parties, including representatives of academia, professional societies, patient advocates, public health organizations, relevant Federal departments and agencies, drug developers, representatives of other relevant industries, and subject matter experts.

(d) Report.—Not later than 2 years after the date of enactment of this Act, the National Academies 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 study conducted pursuant to subsection (a).
TITLE IV—STRENGTHENING BIOSECURITY

SEC. 401. TREATMENT OF GENETIC VARIANTS AND SYNTHETIC PRODUCTS OF SELECT AGENTS AND TOXINS.

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

“(C) INCLUSIONS.—

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

“(I) Any biological agent that incorporates nucleic acids coding for a virulence factor from a listed agent or toxin.

“(II) Any biological agent or toxin that is genetically homologous to a listed agent or toxin with respect to nucleotides coding for virulence factors or toxicity.

“(III) Any biological agent or toxin that is synthetically derived with
virulence or toxicity characteristics of
a listed agent or toxin.

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

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

SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYS-
TEM.

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

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

“(a) Definitions.—In this section:

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

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

“(b) Establishment.—
“(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Response Act, the Secretary shall establish a confidential, anonymous, voluntary, no-fault reporting system related to accidents, near-accidents, or other safety incidents involving biological agents and toxins, in order to support continuous improvement and sharing of lessons learned related to such incidents.

“(2) AVAILABILITY.—The ability to submit reports on a voluntary basis to the reporting system shall be made available to individuals affiliated with laboratories located in the United States, or at federally-funded entities outside the United States, that conduct research involving biological agents and toxins.

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

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

“(B) procedures and processes for the submission of reports;
“(C) criteria for incidents that may be reported to such system; and

“(D) procedures for privacy and anonymization.

“(4) PROTOTYPING AND TESTING.—The Secretary shall test and prototype the reporting system for not less than 1 year before finalizing the reporting system.

“(5) EXTERNAL FEEDBACK.—The Secretary shall seek feedback on development of the reporting system from external stakeholders, including prior to publication of the information under paragraph (3) and prior to introduction of prototypes and finalization of such system under paragraph (4).

“(c) FOIA.—

“(1) IN GENERAL.—Information submitted to, or derived from, the reporting system shall be exempt from disclosure under section 552 of title 5, United States Code.

“(2) APPLICABILITY.—For purposes of paragraph (1), this section shall be considered a statute described in section 552(b)(3)(B) of title 5, United States Code.

“(d) PROHIBITION ON USE AS EVIDENCE.—Information submitted to, or derived from, the reporting system
shall not be used in any Federal or State enforcement action or criminal prosecution.

“(e) Privacy; Disciplinary Action for Unauthorized Disclosure.—An individual or entity that submits information to the reporting system under subsection (b) shall not be required to provide their name.

“(f) Relationship to Other Reporting Systems.—The voluntary reporting system established under this section shall supplement, and not supplant, any other requirements to submit reports under any other reporting system.”.

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

(a) In General.—Not later than 4 years after the date of enactment of this Act, the National Science Advisory Board for Biosecurity (referred to in this section as the “Board”) established pursuant to section 404O of the Public Health Service Act (42 U.S.C. 283r) shall be charged with assessing the framework for biosafety and biosecurity oversight, particularly with respect to mitigating risks to the United States population with respect to biological threats. The findings of the Board shall address scientific advancements and integration of the Program and other related Federal policies and frameworks
for biosafety and biosecurity. The findings of the Board shall be transmitted to the President.

(b) Framework.—

(1) In general.—The recommendations developed under subsection (a) shall include a proposed framework for an integrated approach to the oversight of biological research that raises significant biosafety and biosecurity concerns, which may include proposals to harmonize and modernize relevant Federal policies such as the following:

(A) The Federal Select Agent Program.
(B) Federal policies relating to dual-use research of concern.
(C) Federal policies related to federally-funded research involving enhanced pathogens of pandemic potential.
(D) The Biosafety in Microbiological and Biomedical Laboratories Manual of the Department of Health and Human Services, and other related guidance documents.
(E) The Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules of the National Institutes of Health.

(2) Requirements for framework.—The framework proposed under paragraph (1) shall—
(A) be developed in consultation with stakeholders and experts from institutions of higher education, industry, and other government agencies; and

(B) make recommendations related to mitigating any identified risks associated with existing gaps in oversight of such research, which may include research that does not receive Federal funding, taking into consideration any national security concerns, the potential benefits of such research, considerations related to the research community, transparency, and public availability of information, and international research collaboration.

(c) REORGANIZATION.—In carrying out this section, the Board may make recommendations related to the clarification of the authorities and responsibilities of relevant Federal departments and agencies and any necessary reorganization of such authorities and responsibilities among such departments and agencies.

(d) REPORT.—Not later than 1 year after the issuance of recommendations under subsection (a), the President 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 Rep-
resentatives, and, as applicable, other appropriate commit-
tees of Congress, a report that describes plans to consider
and implement such recommendations, including the iden-
tification of—

(1) any barriers to implementation; and

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

SEC. 404. SUPPORTING RESEARCH AND LABORATORY
SURGE CAPACITY.

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

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

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

(3) supporting information-sharing between,
and the dissemination of findings to, researchers and
other relevant individuals to facilitate collaboration
between industry and academia; and
(4) providing, as appropriate and applicable, technical assistance and training to researchers and other relevant individuals to support the biomedical research workforce in improving the management and mitigation of safety and security risks in the conduct of research involving such biological agents.

(b) REQUIREMENTS.—As a condition of receiving a grant under this section, a regional biocontainment laboratory shall agree—

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

(2) to report accidents, near-accidents, or other safety incidents involving biological agents and toxins into the no-fault reporting system established pursuant to section 351B of the Public Health Service Act, as added by section 402.

(c) BOARD.—The Secretary shall establish a Board consisting of a representative from each entity in receipt of an award under subsection (a), which shall be headed by an executive committee of 3 members elected upon an
affirmative vote from a majority of such representatives. The Board shall make recommendations to the Secretary in administering awards under this section, for purposes of—

(1) improving the quality and consistency of applicable procedures and practices within laboratories funded pursuant to subsection (a); and

(2) ensuring coordination, as appropriate, of federally-funded activities carried out at such laboratories.

(d) Definition.—In this section, the term "regional biocontainment laboratory" means a Biosafety or Animal Biosafety Level-3 and Level-2 facility located at an institution in the United States that is designated by the Secretary to carry out the activities described in subsection (a).

(e) Authorization of Appropriations.—To carry out this section, there are authorized to be appropriated $52,000,000 for each of fiscal years 2024 through 2028.

(f) Administrative Expenses.—Of the amount available to carry out this section for a fiscal year, the Secretary may use not more than 5 percent for the administrative expenses of carrying out this section, including expenses related to carrying out subsection (e).
(g) Report to Congress.—Not later than 1 year after the date of the enactment of this Act, and biannually thereafter, the Secretary, in consultation with the heads of applicable Federal departments and agencies 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—

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

(2) any published or disseminated research findings based on research conducted in such laboratories in the applicable year;

(3) oversight activities carried out by the Secretary pursuant to subsection (b);

(4) activities undertaken by the Secretary to take into consideration the capacity and capabilities of the network of regional biocontainment laboratories in activities to prepare for and respond to biological agents, which may include leveraging such capacity and capabilities to support the Laboratory Response Network, as applicable and appropriate;

(5) plans for the maintenance and sustainment of federally-funded activities conducted at the regional biocontainment laboratories, consistent with the strategy required under section 2312 of the
PREVENT Pandemics Act (Public Law 117–328);

and

(6) activities undertaken by the Secretary to coordinate with applicable agencies to ensure work carried out by such facilities is prioritized and complementary to one another, and avoiding unnecessary duplication.

SEC. 405. GENE SYNTHESIS.

(a) 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 section as the “Secretary”) shall update the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA to account for scientific and technological advancements with respect to mitigating risk of unauthorized individuals or individuals with malicious intent from using nucleic acid synthesis technologies to obtain biological agents or toxins of concern. Such guidance shall include recommendations related to—

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

(2) screening and verification of the identity and legitimacy of customers;
(3) the identification, evaluation, and use of appropriate software or other tools to enable the screening described in paragraphs (1) and (2);

(4) ensuring nucleic acid synthesis activities are carried out in compliance with existing regulations under part 73 of title 42, Code of Federal Regulations, part 331 of title 7, Code of Federal Regulations, part 121 of title 9, Code of Federal Regulations, and part 774 of title 15 Code of Federal Regulations (or successor regulations);

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

(6) maintaining records of customer orders, metadata, and screening system or protocol performance in specified formats, which may include standardized machine-readable and interoperable data formats; and

(7) other recommendations as determined appropriate by the Secretary.

(b) SEQUENCES OF CONCERN.—The Secretary shall maintain a public docket to solicit recommendations on potential sequences of concern and, in consultation with other Federal departments and agencies and non-Federal...
experts, as appropriate, review and update, on a regular basis, a list of sequences of concern to facilitate screening under subsection (a)(1).

(e) LANDSCAPE REVIEW.—The Secretary, in coordination with other Federal departments and agencies, as appropriate, shall conduct a landscape review of providers and manufacturers of gene synthesis equipment, products, software, and other tools with the purpose of understanding the number, types, and capabilities of products and equipment that exist domestically and to inform the development of any updates to the guidance under subsection (a).

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

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

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

(2) The term “gene synthesis product”—
(A) means custom single-stranded or double-stranded DNA, or single-stranded or double-stranded RNA, which has been chemically or enzymatically synthesized or otherwise manufactured de novo and is of a length exceeding the screening threshold, as determined by the Secretary; and

(B) does not include—

(i) base chemical subunits, such as individual nucleotides or nucleosides, or oligonucleotides shorter than the screening threshold typically used as polymerase chain reaction primers, as determined by the Secretary; or

(ii) by-products generated during sequencing that are not useful for assembly or cloning, as determined by the Secretary.

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

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

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

SEC. 406. LIMITATION RELATED TO COUNTRIES OF CONCERN CONDUCTING CERTAIN RESEARCH.

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

(1) in paragraph (1)—

(A) by inserting “that may reasonably be anticipated to involve the creation, transfer, and use of enhanced pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) if such research is” after “not fund research”; and

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

(2) in paragraph (2)—

(A) in the heading, by striking “CONDITIONS FOR LISTING OR SUSPENDING PROHIBITION” and inserting “LIMITATIONS”; and
(B) in the matter preceding subparagraph

(A)—

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

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

and

(3) by adding at the end the following:

“(3) CLARIFICATION.—

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

“(B) NOTIFICATION.—The President shall
notify Congress not later than 48 hours after
exercising the waiver under subparagraph (A),
and shall provide updates to Congress related to
the use of such waiver every 15 days there-
after.”.
SEC. 407. ASSESSMENT OF ARTIFICIAL INTELLIGENCE THREATS TO HEALTH SECURITY.

(a) In General.—Not later than 45 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 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 assessing the potential vulnerabilities to health security presented by the current or prospective use or misuse of artificial intelligence, including with respect to open-source artificial intelligence models, such as large language models.

(b) Inclusions.—The study conducted pursuant to the contract under subsection (a) shall include—

(1) an assessment of the potential vulnerabilities posed by technical advancements in artificial intelligence to health security, including any risks related to the development of, enhancement of, or protection from, chemical, biological, radiological, or nuclear threats;

(2) a description of roles, responsibilities, and capabilities of agencies and offices of the Department of Health and Human Services, and, as applicable and appropriate, other Federal departments
and agencies, with respect to the identification and
mitigation of such potential vulnerabilities;

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

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

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

(c) REPORTS.—

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

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

TITLE V—PREVENTING DRUG SHORTAGES

SEC. 501. IMPROVING NOTIFICATION PROCEDURES IN CASE OF INCREASED DEMAND FOR CRITICAL DRUGS.

(a) In General.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) is amended—

(1) in the section heading, by striking “DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS” and inserting “NOTIFICATION OF ISSUES AFFECTING DOMESTIC SUPPLY OF CRITICAL DRUGS”;  

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

“(a) Notification Required.—

“(1) In General.—A manufacturer of a covered drug shall notify the Secretary, in accordance with subsection (b), of—

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

“(ii) a permanent discontinuance in the manufacture of an active pharmaceutical ingredient of such drug, or an interruption in the manufacture of an active pharmaceutical ingredient of such drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of such drug; or

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

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

“(2) CONTENTS.—Notification under this subsection with respect to a covered drug shall include—

“(A) with respect to the reasons for the discontinuation, interruption, or other circumstance described in paragraph (1)(A)(iii), if an active pharmaceutical ingredient is a reason for, or risk factor in, such discontinuation,
interruption, or other circumstance, the source of the active pharmaceutical ingredient and any alternative sources for the active pharmaceutical ingredient known to the manufacturer;

“(B) whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, such discontinuation, interruption, or other circumstance described in paragraph (1)(A)(iii);

“(C) the expected duration of the interruption; and

“(D) such other information as the Secretary may require.

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

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

“(2) in the case of such a notice with respect to a circumstance described in subsection (a)(1)(A)(iii), as soon as practicable, or not later than 10 business days after the onset of the circumstance; or

“(3) if compliance with paragraph (1) or (2) is not possible, as soon as practicable.
“(c) DISTRIBUTION.—To the maximum extent prac-
ticable, the Secretary shall distribute, through such means
as the Secretary determines appropriate, information on
the discontinuance or interruption of the manufacture of,
or other circumstance described in subsection
(a)(1)(A)(iii) that is likely to lead to a shortage or mean-
meaningful disruption in the supply of, covered drugs to appro-
appropriate organizations, including physician, health provider,
and patient organizations, as described in section 506E.”;

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

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

(b) DEFINITIONS.—Paragraph (1) of section 506C(h)
356c(h)) is amended to read as follows:

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

“(A) is—

“(i) life-supporting;
“(ii) life-sustaining; or
“(iii) intended for use in the preven-
tion or treatment of a debilitating disease
or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act;

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

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

SEC. 502. REPORTING ON SUPPLY CHAINS.


(1) by inserting “, and the names and unique facility identifiers of the manufacturers of the active pharmaceutical ingredients such person used for the manufacture, preparation, propagation, compounding, or processing of such drug, and the amount of such drug manufactured, prepared, propagated, compounded, or processed using each such
active pharmaceutical ingredient from each such
manufacturer” before the period at the end of the
first sentence; and

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

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

Not later than 90 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 report
to the Committee on Health, Education, Labor, and Pen-
sions of the Senate and the Committee on Energy and
Commerce of the House of Representatives on—

(1) the extent to which the Secretary has imple-
mented the authorities and requirements under sec-
tions 506C(g), 506C(j), 506E(d), 510(j)(3), and
704(b)(2) (21 U.S.C. 356c(g), 356c(j), 356c(d),
360(j)(3), 374(b)(2)) of the Federal Food, Drug,
and Cosmetic Act, as amended by section 3111 and
3112 of the Coronavirus Aid, Relief, and Economic
Security Act (Public Law 116–136), including—
(A) specific examples of uses of such authorities and requirements; and

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

(2) the status of the guidance documents that the Secretary intends to issue with respect to reporting and risk management plan requirements applicable to manufacturers of drugs and active pharmaceutical ingredients, pursuant to the amendments made to section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) by subsections (a) and (b) of section 3112 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136).

TITLE VI—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

SEC. 601. MEDICAL COUNTERMEASURE PRIORITY REVIEW VOUCHER.

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

SEC. 602. EPIDEMIC INTELLIGENCE SERVICE LOAN REPAYMENT PROGRAM.

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

SEC. 603. VACCINE TRACKING AND DISTRIBUTION.

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

SEC. 604. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

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

SEC. 605. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONAL.

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

SEC. 606. LIMITED ANTITRUST EXEMPTION.

Section 319L–1(b) of the Public Health Service Act (42 U.S.C. 247d–7f(b)) is amended by striking “at the end of the 17-year period that begins on the date of enactment of this Act” and inserting “on September 30, 2028”.
SEC. 607. TRAUMA CARE.

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

SEC. 608. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS.

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

SEC. 609. NATIONAL DISASTER MEDICAL SYSTEM.

(a) In General.—Section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) is amended—

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

(2) in subsection (g), by striking “$57,400,000 for each of fiscal years 2019 through 2023” and inserting “$65,900,000 for each of fiscal years 2024 through 2028”.

(b) Repeal of Sunset.—

(1) In General.—Section 301(d)(3) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law 116–22; 34 U.S.C. 10284 note) is repealed.
(2) EFFECTIVE DATE.— Paragraph (1) shall take effect as if enacted on September 30, 2021.

SEC. 610. VOLUNTEER MEDICAL RESERVE CORPS.

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

SEC. 611. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.

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

SEC. 612. VETERANS AFFAIRS.

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

SEC. 613. TECHNICAL AMENDMENTS.

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

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

(2) in section 2110(b), by striking “the program” and inserting “The Program”;

(3) in section 2111(a)—
(A) in paragraph (6), by striking “1988 for” and inserting “1988, for”; and
(B) in paragraph (10), by striking “United States Claims Court” and inserting “United States Court of Federal Claims”;

(4) in section 2112—
(A) in subsection (e)(6)(A), by striking “United States Claims Courts” and inserting “United States Court of Federal Claims”; and
(B) in subsection (f)—
(i) by striking “United States Claims Court on” and inserting “United States Court of Federal Claims on”; and
(ii) by striking “United States Claims Court’s judgment” and inserting “judgment of the United States Court of Federal Claims”;

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

(6) in section 2117—
(A) in the section heading, by striking “SUBROGRATION” and inserting “SUBROGA-
TION”; and
(B) in subsection (a), by striking “subrograted” and inserting “subrogated”; and
(7) in section 2127—

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

(B) in subsection (c), by striking “Committee on Labor and Human Resources” and inserting “Committee on Health, Education, Labor, and Pensions”.

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

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

(2) in subsection (i)(7)—

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

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

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

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

(2) in subsection (d)(5), by striking “under subsection (a) the Secretary determines that a covered individual qualifies for compensation” and inserting “a covered individual is determined under
subsection (a) to be eligible for compensation under this section’.

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

(1) in section 261(a)(2)(A), by striking “specialties” and inserting “specialties’’;

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

(3) in section 266(b)(3)(B)(ii), by striking “to with respect to an eligible” and inserting “with respect to an eligible’’; and

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

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