# Calendar No. 202

118TH CONGRESS
1ST SESSION

# S. 2333

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

JULY 18, 2023

Mr. CASEY (for himself, Mr. ROMNEY, Mr. SANDERS, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 6, 2023

Reported by Mr. SANDERS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

---

# 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.

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

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

(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness and Response Act".

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

# TITLE I—STATE AND LOCAL READINESS AND RESPONSE

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

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

(1) in paragraph (1), by striking ''such Governor or tribal organization's designee'' and insert-

ing ''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 entity pursuant to paragraph (5) for noncompliance 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)''; and

(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 entities, such as coalitions that include emergency 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 subsection (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

(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'';

(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 REQUIREMENTS.—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 inform 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 (i), by striking ''and in consultation with the Secretary of Homeland Security,''; and

(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 semicolon;

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

(IV) by adding at the end the following:

''(iv) that include, as appropriate, 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 subparagraph (A), by inserting ''and the requirements 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 countermeasure 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 Secretary for Preparedness and Response shall develop and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a 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 distribution 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 organizations, and other relevant public and private entities.

"(c) CAPACITY BUILDING.—The Secretary may contract with public and private entities, as appropriate, to increase domestic capacity in the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an 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 following:

''(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 appropriate, 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.

“(ix) The Administrator of the Centers for Medicare & Medicaid Services.

“(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; and

"(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) NONDUPLICATION 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 paragraph (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 bacteria and fungi and prevent the spread of resistant infections;

"(B) strengthen activities to combat resistance 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 prevention, detection, and control.";

(D) by redesignating paragraph (4) as paragraph (5); and

(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

(B) by inserting ", not later than 60 days after such determination";

(3) in subsection (f)(1), by striking "$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023" and inserting "$965,000,000 for each of fiscal years 2024 through 2028"; and

(4) in subsection (g)(1), by striking "2019 through 2028" and inserting "2024 through 2033".

**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(c)) 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 members; and

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

(A) expertise in public health, including individuals with experience in State, local, and Tribal health departments, medicine, communications, related technology, psychology, mental health and substance use disorders, national security;

(B) experience in leading community outreach; or

(C) expertise in other areas, as the Secretary 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 subsection (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 noncompetitively 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 (c) 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 amended—

(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 following:

''(B) EXCLUSION OF INJURIES CAUSED BY VACCINES ON THE VACCINE INJURY TABLE.—Notwithstanding any other provision of this section, 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 ''unless 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 striking ''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 following:

''(4) LICENSURE REQUIREMENT.—Notwithstanding paragraphs (2) and (3), the Secretary may not revise the Vaccine Injury Table to include a vaccine 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 administration or use was filed before the date of enactment 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 administration of a COVID–19 vaccine, such a claim may be filed under the Program only if the administration of such vaccine occurred prior to the addition of the vaccine to the Vaccine Injury Table under section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14).

(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 Service 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 General, shall submit a budget outlining the resource 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-

priate, 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, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170, 5191) to ensure that such standards of care are consistent with the nondiscrimination requirements of section 504 of the Rehabilitation 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''; 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''; 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)—

(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 following:

~~"(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 redesignated, 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 research; and

(3) establish a primary care technical assistance initiative to convene primary care providers and organizations, which may include support for con-

tinuing 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; and

(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 encodes for components contributing to pathogenicity, transmissibility, or toxicity 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 subparagraph (B).''.

**SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYSTEM.**

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

**''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 reporting 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).

‘‘(e) 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 committees of Congress, a report that describes plans to consider and implement such recommendations, including the identification 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 "Secretary") shall make awards to establish or maintain, as applicable, not fewer than 12 regional biocontainment laboratories, for purposes of—~~

~~(1) conducting biomedical research to support public health and medical preparedness for, and rapid response to, biological agents, including emerging 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).

(c) 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;

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

(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 synthesis 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 initial 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 requirement impedes the ability of the Federal Government 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 thereafter.''.

**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 activities 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 Energy and Commerce of the House of Representatives a report on the study conducted pursuant to subsection (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 Senate 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. 356c) 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 practicable, 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 meaningful disruption in the supply of, covered drugs to 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 subsection (a)'' and inserting ''covered drug''; and

(4) in subsection (j), by striking ''drug described in subsection (a)'' and inserting ''covered drug''.

(b) DEFINITIONS.—Paragraph (1) of section 506C(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 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 prevention 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.**

Section 510(j)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—

(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 following: ''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 Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the extent to which the Secretary has implemented the authorities and requirements under sections 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(e)(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–3e(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 (c)(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 (c)'' and inserting ''subsection (c))'';

(6) in section 2117—

(A) in the section heading, by striking ''**SUBROGRATION**'' and inserting ''**SUBROGATION**''; 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)''; and

(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 H of the Public Health Service Act (42 U.S.C. 239 et seq.) is amended—

(1) in section 261(a)(2)(A), by striking ''specialities'' 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".~~

~~(c) Section 351A(e)(7)(B)(ii) is amended by striking "judical" and inserting "judicial".~~

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

*(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness and Response Act".*

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

# *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 "tribal organization or such Governor or tribal organization's designee" and inserting "Tribal organization or 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 subparagraph (A), 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 entity pursuant to paragraph (5) for noncompliance 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 sec-*

*tion or section 319C–2" after "paragraph (5)"; and*

*(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 2007, the Secretary" and inserting "The Secretary"; and*

*(ii) in subparagraph (D), by striking "for fiscal year 2006"; 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 a 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 "(1) LOCAL RESPONSE CAPABILITIES" 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 other eligible entities, such as 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 subsection (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*

*(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 103(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, among 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 among 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";*

*(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 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 enti-*

*ties 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 monitoring, 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 the following:*

*"(B) DEVELOPMENT OF REQUIREMENTS.—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 inform the advanced research, development, procurement, and replenishment decisions of the Secretary.";*

*(B) in paragraph (4)—*

*(i) in subparagraph (F)—*

*(I) in the matter preceding clause (i), by striking "and in consultation with the Secretary of Homeland Security,"; and*

*(II) in clause (i), by inserting "enhance" after "capabilities 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 semicolon;*

*(III) in clause (iii), by striking the period and inserting "; and"; and*

*(IV) by adding at the end the following:*

*"(iv) that include, as appropriate, 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 Pre-*

*paredness 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 subparagraph (A), by inserting "and the requirements 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 countermeasure 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 Secretary for Preparedness and Response shall develop and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a 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 diseases, 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 Preparedness 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—*

*"(A) may be used to improve testing capabilities, including—*

*"(i) high-throughput laboratory diagnostics; and*

*"(ii) point-of-care diagnostics;*

*"(B) improve the accessibility of diagnostic tests; and*

*"(C) 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 distribution of tests locally, regionally, or nationwide and scaling of laboratory testing capacity; and*

*"(5) assessment of 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 organizations, and other relevant public and private entities.*

*"(c) CAPACITY BUILDING.—The Secretary may contract with public and private entities, as appropriate, to increase domestic capacity in the rapid development, validation, authorization, manufacture, procurement, and distribution of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an 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 shall 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 following:*

*"(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 appropriate, 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 is 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),*

*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.*

*"(ix) The Administrator of the Centers for Medicare & Medicaid Services.*

*"(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,*

*and 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) NONDUPLICATION OF EFFORT.—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.***

*(a) IN GENERAL.—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 paragraph (4)," after "comprehensive plan";*

*(C) by amending paragraph (3) to read as follows:*

*"(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 bacteria and fungi and prevent the spread of resistant infections;*

*"(B) strengthen activities to combat resistance 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 prevention, 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—*

*"(A) the agenda described in paragraph (3);*

*"(B) input provided by the Advisory Council described in subsection (b); and*

*"(C) input from 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 frequently 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)".*

*(b) CONFORMING AMENDMENT.—Section 505 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public Law 116–22) is amended by striking subsection (a) and all that follows through "Not later" in subsection (e) and inserting the following:*

*"Not later".*

***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)—*

*(i) in subclause (II), in the matter preceding item (aa), by inserting "including prioritizing such goals and identifying metrics to measure success in meeting such goals," after "information),"; and*

*(ii) 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 bio-*

*logical 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;";*

*(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) in subparagraph (I), by inserting ", through a standard operating procedure," after "ensure";*

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

*(iv) by inserting after subparagraph (G) the following:*

*"(H) utilize tools to enable the timely and accurate tracking of the contents of the stockpile throughout the deployment of such contents, including tracking of the location and geographic*

*distribution and utilization of such contents;"; and*

*(C) in paragraph (5)(B), in the matter preceding clause (i), by inserting ", which may accompany the review required under paragraph (2)," after "Representatives a report";*

*(2) in subsection (c)(2)(C)—*

*(A) by striking "promptly"; and*

*(B) by inserting ", not later than 60 days after each such determination,";*

*(3) in subsection (f)(1), by striking "$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023" and inserting "$965,000,000 for each of fiscal years 2024 through 2028"; and*

*(4) in subsection (g)(1), by striking "2019 through 2028" and inserting "2024 through 2033".*

***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) 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)(ii), by inserting "or priority virus families and other viral pathogens that pose a threat due to their signifi-*

*cant potential to cause a pandemic," after "pandemic influenza,";*

*(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(c)) 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 members; and*

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

*(A) expertise in public health, including through experience in State, local, and Tribal health departments, medicine, communications, related technology, psychology, mental health and substance use disorders, or national security;*

*(B) experience in leading community outreach; or*

*(C) expertise in other areas, as the Secretary 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 subsection (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.*

*(e) 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 noncompetitively 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 such 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 recommendations on how to improve future responses.*

***SEC. 212. EMERGING PATHOGENS PREPAREDNESS PROGRAM.***

*(a) IN GENERAL.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended by adding at the end the following:*

*"(j) EMERGING PATHOGENS PREPAREDNESS PROGRAM.—*

*"(1) IN GENERAL.—The Secretary shall establish a program to facilitate the development, review, licensure, approval, and clearance of countermeasures, and products that could potentially be countermeasures, under the jurisdiction of the Center for Biologics Evaluation and Research.*

*"(2) ACTIVITIES.—The activities of the program established under paragraph (1) may include, either directly or by grant, contract, or cooperative agreement, the following:*

*"(A) Any activities described in subsection (b).*

*"(B) Activities to advance scientific research related to the development of tools, standards, and approaches to assess the safety, efficacy, quality, and performance of countermeasures.*

*"(C) Activities to maintain or enhance surveillance programs that monitor countermeasures.*

*"(D) Activities to help ensure blood safety and availability.*

*"(E) Prioritizing the research and development of platform vaccine technologies to support an emergency use authorization request under section 564 or an application under section 351(a) of the Public Health Service Act.*

*"(F) Such other activities as the Secretary determines necessary or appropriate.*

*"(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to license, approve, clear, or authorize countermeasures, including biological products, pursuant to section 351 of the Public Health Service Act or section 505 or 564 of this Act, including standards of evidence and applicable conditions for licensure, approval, clearance, or authorization.".*

*(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out subsection (j) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as added by subsection (a), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2024 through 2028.*

# *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 subparagraph (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 (42 U.S.C. 247d–6e) 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(b)) with respect to the same vaccine administration claimed in the petition submitted*

*under section 2111 of such Act (42 U.S.C. 300aa–11)—*

*(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 1 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 amended—*

*(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 following:*

*"(B) EXCLUSION OF INJURIES CAUSED BY VACCINES ON THE VACCINE INJURY TABLE.—Notwithstanding any other provision of this section, no individual may be eligible for compensation 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 information required under subsection (c)" after "unless 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 striking "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 following:*

*"(4) LICENSURE REQUIREMENT.—Notwithstanding paragraphs (2) and (3), the Secretary may not revise the Vaccine Injury Table to include a vaccine 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) 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".*

*(b) DETERMINATION OF GOOD FAITH.—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 Countermeasures 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 such section 319F–4, the claim shall be filed within 3 years of the administration or use of the covered countermeasure, or 1 year after the date of enactment of this Act, whichever is later, and, if a claim filed under the Program with respect to such administration or use was filed before the date of enactment 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 administration of a COVID–19 vaccine, such a claim may be filed under the Program only if the administration of such vaccine occurred prior to the addition*

*of the vaccine to the Vaccine Injury Table under section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14).*

*(3) Not later than 9 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish a notice of proposed rulemaking establishing a covered countermeasure injury table pursuant to section 319F–4(b)(5) of the Public Health Service Act (42 U.S.C. 247d–6e(b)(5)).*

*(b) 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 Countermeasures 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 whether 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 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 purposes 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 subawards.*

*(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 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 effect 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, respectively, of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170, 5191) to ensure that such*

*standards of care are consistent with the nondiscrimination requirements of section 504 of the Rehabilitation 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"; 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"; 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)—*

*(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) and (L) as subparagraphs (L) and (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 following:*

*"(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 redesignated, 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 infection, 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 (2), 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 research; and*

*(3) establish a primary care technical assistance initiative to convene primary care providers and organizations, which may include support for 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 ex-*

*panded 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; and*

*(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;*

*(D) health outcomes;*

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

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

*(G) Federal discretionary and mandatory spending; and*

*(H) 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.—The following shall be considered to be a biological agent or toxin included on the list under this paragraph:*

*"(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 encodes for components contributing to pathogenicity, transmissibility, or toxicity 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 subparagraph (B).".*

***SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYSTEM.***

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

***"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 reporting 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 over-*

*sight, 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 Federal Select Agent 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 Representatives, and, as applicable, other appropriate committees of Congress, a report that describes plans to consider and implement such recommendations, including the identification 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 "Secretary") shall make awards to establish or maintain, as applicable, not fewer than 12 regional biocontainment laboratories, for purposes of—*

*(1) conducting biomedical research to support public health and medical preparedness for, and rapid response to, biological agents, including emerging 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 to—*

*(1) 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) 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 administra-*

*tive expenses of carrying out this section, including expenses related to carrying out subsection (c).*

*(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 the heads of other relevant Federal departments and agencies to ensure that work carried out by each such facility on behalf of the Secretary and such other relevant heads is prioritized, is complementary to the work carried out by other such facilities and other relevant federally funded activities, and avoids 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 the risk of unauthorized individuals or individuals with malicious intent 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 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 po-*

*tential 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).*

*(c) 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—*

*(I) individual nucleotides or nucleosides; or*

*(II) oligonucleotides shorter than such screening threshold as is determined by the Secretary;*

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

*(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 to or notice of the sequence design, as determined by the Secretary.*

*(3) The term ''gene synthesis provider'' means an entity that synthesizes and distributes gene synthesis*

*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 initial determination of a country of concern pursuant to paragraph (1), 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 requirement impedes the ability of the Federal Government 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 thereafter.".*

***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 activities 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 Energy and Commerce of the House of Representatives a report on the study conducted pursuant to subsection (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 Senate 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. 356c) 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 alter-*

*native 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 practicable, 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 meaningful disruption in the supply of, covered drugs to 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 subsection (a)" and inserting "covered drug"; and*

*(4) in subsection (j), by striking "drug described in subsection (a)" and inserting "covered drug".*

*(b) DEFINITIONS.—Paragraph (1) of section 506C(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 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 prevention 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 emer-*

*gency 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.***

*Section 510(j)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—*

*(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 following: "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 Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—*

*(1) the extent to which the Secretary has implemented the authorities and requirements under sections 506C(g), 506C(j), 506E(d), 510(j)(3), and 704(b)(2) (21 U.S.C. 356c(g), 356c(j), 356e(d), 360(j)(3), 374(b)(2)) of the Federal Food, Drug, and Cosmetic Act, as amended by sections 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(c)(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.***

*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".*

***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 (c)(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 "**SUBROGATION**"; 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)"; and*

*(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) Section 319I of the Public Health Service Act (42 U.S.C. 247d–7b) is amended, in the section heading, by striking "**PROFESSIONAL**" and inserting "**PROFESSIONALS**".*

*(e) 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 "specialities" 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".*

*(f) Section 351A(e)(7)(B)(ii) is amended by striking "judical" and inserting "judicial".*

**Calendar No. 202**

118TH CONGRESS
1ST SESSION

# S. 2333

# 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.

SEPTEMBER 6, 2023

Reported with an amendment