118TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____

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

A BILL

[To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic 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 [''2023 Reauthorization of the Pandemic and All-Hazards Preparedness 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. 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)(1)(A), by striking ''$685,000,000 for each of fiscal years 2019 through 2023'' and inserting ''[$685,000,000] for each of fiscal years 2024 through 2028''.

SEC. 102. 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 underrepresented eligible entities described in subsection (b)(1)(A), such as 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. 103. IMPROVING MEDICAL READINESS AND RESPONSE CAPABILITIES.

The Public Health Service Act is amended—

(1) in section 319C–2 (42 U.S.C. 247d–3b)—

(A) in subsection (b)(2)—

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

(ii) in subparagraph (B), by striking the period and inserting ''; and''; and

(iii) by inserting at the end the following:

''(C) designate a lead entity, which shall not be a component of an eligible entity that is responsible for carrying out regulatory activities related to health care facilities within the applicable State or political subdivision of a State, to administer such award and support coordination between entities described in this subsection.'';

(B) 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

(C) in subsection (j)(1)(A), by striking ''$385,000,000 for each of fiscal years 2019 through 2023'' and inserting ''[$385,000,000] for each of fiscal years 2024 through 2028''; and

(2) in section 2802(b) (42 U.S.C. 300hh–1(b))—

(A) in paragraph (3)(C), by inserting ''and current capacity of facilities within such systems, as applicable'' before the period;

(B) in paragraph (5), by inserting ''applicable federally-funded activities and'' after ''(including''; and

(C) 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,''.

SEC. 104. 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 supbaragraph (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; and

''(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

(4) 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. 105. 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 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 use amounts awarded under this section to—

"(1) establish, or enhance existing, capacity and capabilities to conduct wastewater sampling 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 and 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. 106. 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.—

''(1) TECHNICAL ASSISTANCE.—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.

''(2) EDUCATION.—[A recipient of an award under [subsection (a) or (b)] may use up to [5] percent of the total amount provided for each fiscal year to provide continuing education and training for individuals carrying out activities pursuant to such award, including training and support for any applicable public health entomologists.]''; and

(4) in subsection (f)(1), by striking ''$100,000,000 for each of fiscal years 2019 through 2023'' and inserting ''[$100,000,000] for each of fiscal years 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, procurement, 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 insert-

ing ‘‘, including needs for active pharmaceutical ingredients, key starting materials, and other critical components of such products and supplies,’’ 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 '', includ-

ing 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 ''[$250,000,000] for each of fiscal years 2024 through 2028''.

SEC. 202. 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, 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, of the contents of the stockpile throughout the deployment of such contents;''; and

(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 (g)(1), by striking " $7,100,000,000 for the period of fiscal years 2019 through 2028" and inserting "[$7,100,000,000] for the period of fiscal years 2024 through 2033".

SEC. 203. MEDICAL COUNTERMEASURES FOR VIRAL THREATS WITH PANDEMIC POTENTIAL.

(a) IN GENERAL.—Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amended—

(1) 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

(2) in subparagraph (F)(ii), by inserting ''priority virus families, and other viral pathogens with a significant potential to cause a pandemic,'' after ''pandemic influenza,''.

SEC. 204. 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 (2), by striking '', as appropriate''; and

(2) 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 devel-

oped under subparagraphs (A) and (C) of paragraph (1) with relevant stakeholders, including industry and State, local, and Tribal public health departments.''.

SEC. 205. 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 aggregation 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; and

(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 bidirectional communication between agencies and offices of the Department of Health and Human Services and State, local, and Tribal public health officials.''; and

(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 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'';

(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 GUIDANCE.—For purposes of this subsection, the Secretary shall develop guidance on 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 guidance under this subsection, the Secretary shall—

''(A) adopt 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; and

''(B) 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).

(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—

''(A) [the implementation of data and information sharing under section 310B]; and

''(B) 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.

"(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 care data;

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

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

"(c) SUNSET.—This section shall cease to have force or effect on September 30, 2028.".

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

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

(a) TREATMENT OF INELIGIBILITY OF CERTAIN 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(b)(4) of the Public Health Service Act (42 U.S.C. 247d–6e(b)(4)) for an injury or death related to a COVID–19 vaccine that the Secretary determines to be ineligible for the program 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 injury claimed in the request submitted under section 319F–4(b)(4) of such Act (42 U.S.C. 247d–6e(b)(4)), 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).

(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 and the petitioner is not eligible for compensation pursuant to section 2116(b) of such Act (42 U.S.C. 300aa–16); 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 in-

jury claimed in the petition submitted under section 2111 of such Act—

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

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

(b) CHANGES TO CERTAIN PROGRAMS.—

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

(A) by striking ''Except as provided'' and inserting the following:

''(A) IN GENERAL.—Except as provided''; and

(B) 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 sec-

tion, no individual may be eligible for compensation under this section with respect to a covered injury caused by a vaccine that, at the time it was administered, was included in the Vaccine Injury Table under section 2114.''; and

(C) 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 paragraphs (2) and (3) of 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.''; and]

(D) in section 2116(b) (42 U.S.C. 300aa–16(b))—

(i) in the matter preceding paragraph (1), by striking ''except that no compensation may be provided'' and inserting ''except that no petition may be filed'';

(ii) in paragraph (1)—

(I) by striking ''death'' and inserting ''injury or death''; and

(II) by striking '', or'' and inserting '';''; and

(iii) by striking paragraph (2) and inserting the following:

''(2) the vaccine was administered at a time when the vaccine was a covered countermeasure subject to a declaration under section 319F–3(b); or

''(3) any request for compensation for the same vaccine-related injury or death is pending, or has been resolved, under the program under section 319F–4.''.

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

(a) NATIONAL VACCINE INJURY COMPENSATION PROGRAM.—

[(1) IN GENERAL.—Section 2112(c) of the Public Health Service Act (42 U.S.C. 300aa12(c)) is amended—]

[(A) in paragraph (1), by striking ''not more than 8 special masters'' and inserting ''not fewer than 10 special masters''; and]

[(B) in paragraph (4)—]

[(i) by striking ''a term of 4 years'' and inserting ''an initial term of 4 years'';]

[(ii) by striking the second and third sentences; and]

[(iii) 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).''.]

(2) 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—

(A) in subclause (I), by striking ", and" and inserting a semicolon;

(B) in subclause (II)—

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

(ii) by striking ", or" and inserting "; and"; and

(C) 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".

(3) 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 of the flush text 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.".

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

(1) in subsection (b)(4), as amended by section 301(b), by adding at the end the following:

"(C) TIMING.—

"(i) IN GENERAL.—Each determination made by the Secretary under this paragraph shall be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time, after the date the petition was filed.

"(ii) REQUESTS FOR RECONSIDERATION.—Applications to request reconsideration of a determination in accordance with section 262(f)(1) shall be made within 60 days of notification of the determination. The Secretary shall complete such reconsideration as expeditiously as practicable but not later than 90 days, exclusive of suspended time, after the date on which the reconsideration was requested.";

(2) in subsection (d)—

(A) in paragraph (1) by striking "240 days" and inserting "420 days, exclusive of suspended time,"; and

(B) by adding at the end the following:

''(6) FAILURE TO RESPOND.—If an individual who submits a request for benefits under subsection (a) fails to respond to subsequent requests for information or action, resulting in suspended time of over 240 continuous days or an aggregate period of over 420 days, the request shall be withdrawn and the individual shall not be considered as having exhausted available remedies for purposes of paragraph (1). The Secretary shall make no fewer than 3 attempts to contact the individual prior to a withdrawal, with not fewer than 60 days between each such attempt.''; and

(3) in subsection (e) by adding at the end the following:

''(6) SUSPENDED TIME.—The term 'suspended time' means time during consideration of a request for compensation under subsection (b)(4) during which the Secretary is awaiting further information or documentation from the requesting individual, following notification of the individual by the Secretary that such information or documentation is required to proceed with determination of eligibility and compensation or payment.''.

[(c) *Amendments to Compensation Provided through CICP.*]

SEC. 303. REVIEW OF REGULATIONS.

Not later than 120 days after the date of enactment of this Act, the Secretary of Health and Human Services shall update, as needed for purposes of carrying out the amendments made by this Act, regulations governing administration of 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.) and under the Countermeasures Injury Compensation Program under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e).

SEC. 304. SUPPORTING INDIVIDUALS WITH DISABILITIES 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 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).

(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. 305. 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 Pol-

icy 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 [2] 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 ac-

cessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery.

''(iv) 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. 306. 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, which may include conditions and any effects on 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 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 or-

ganizations, 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.

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 2 years after the date of enactment of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness 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 1 year after the date of enactment of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act, the Secretary shall publish [a notice in the Federal Register on/details and] 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 BSAT REPORTING SYSTEM.—The voluntary reporting system established under this section shall supplement, and not supplant, the mandatory reporting requirements applicable to the misuse of listed agents and toxins.''.

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

(a) IN GENERAL.—Not later than 3 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 evaluate the effectiveness of the Federal Select Agent Program (referred to in this section as the ''Program'') in mitigating risks to the United States population with respect to biological threats and make recommendations to the President related to the modernization of the Program, includ-

ing to address scientific advancements and integration of the Program and other related Federal policies and frameworks for biosafety and biosecurity.

(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 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.

(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 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 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 improve 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) DEFINITION.—In this section, the term ''regional biocontainment laboratory'' means a Biosafety or Animal Biosafety Level-3 or 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).

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated [$52,000,000] for each of fiscal years 2024 through 2028.

(2) ALLOCATION OF FUNDS.—Of the amount appropriated under paragraph (1) for a fiscal year, the Secretary shall allot to each regional biocontainment laboratory receiving a grant under subsection (a) for such fiscal year—

(A) $1,000,000; and

(B) if any amount remains after allocating amounts under subparagraph (A), such additional amounts as the Secretary may determine and award to laboratories on a competitive basis.

(e) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, and annually 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.

TITLE V—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

SEC. 501. 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 ''$1,000,000 for each of fiscal years 2019 through 2023'' and inserting ''**[**$1,000,000**]** for each of fiscal years 2024 through 2028''.

SEC. 502. TEMPORARY REASSIGNMENT OF STATE AND LOCAL PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.

Section 319(e)(8) of the Public Health Service Act (42 U.S.C. 247d(e)(8)) is amended by striking ''2023'' and inserting ''2028''.

SEC. 503. VACCINE TRACKING AND DISTRIBUTION.

Section 319A(e) of the Public Health Service Act (42 U.S.C. 247d–1(e)) is amended by striking ''$30,800,000 for each of fiscal years 2019 through 2023'' and inserting ''**[**$30,800,000**]** for each of fiscal years 2024 through 2028''.

SEC. 504. 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. 505. 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 ''$5,000,000 for each of fiscal years 2019 through 2023'' and inserting ''[$5,000,000] for each of fiscal years 2024 through 2028''.

SEC. 506. 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. 507. 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 [''$24,000,000 for each of fiscal years 2024 through 2028'']].

SEC. 508. 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 ''$11,500,000 for each of fiscal years 2019 through 2023'' and inserting ''[$11,500,000] for each of fiscal years 2024 through 2028''.

SEC. 509. NATIONAL DISASTER MEDICAL SYSTEM.

Section 2812(g) of the Public Health Service Act (42 U.S.C. 300hh–11(g)) is amended by striking ''$57,400,000 for each of fiscal years 2019 through 2023'' and inserting ''[$57,400,000] for each of fiscal years 2024 through 2028''.

SEC. 510. VOLUNTEER MEDICAL RESERVE CORPS.

Section 2813(i) of the Public Health Service Act (42 U.S.C. 300hh–15(i)) is amended by striking ''$11,200,000 for each of fiscal years 2019 through 2023'' and inserting ''[$11,200,000] for each of fiscal years 2024 through 2028''.

SEC. 511. 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 ''$190,000,000 for each of fiscal years 2019 through 2023'' and inserting ''[$190,000,000] for each of fiscal years 2024 through 2028''.

SEC. 512. VETERANS AFFAIRS.

Section 8117(g) of title 38, United States Code is amended by striking ''$155,300,000 for each of fiscal years 2019 through 2023'' and inserting ''[$155,300,000] for each of fiscal years 2024 through 2028''.

SEC. 513. TECHNICAL AMENDMENTS.

(a) VACCINES.—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) PREP AMENDMENTS.—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) COVERED COUNTERMEASURE PROCESS.—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) SMALLPOX EMERGENCY PERSONNEL PROTECTION.—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''.

(e) OTHER AMENDMENT.—Section 351A(e)(7)(B)(ii) is amended by striking ''judical'' and inserting ''judicial''.

TITLE VI—ADDITIONAL POLICIES OUTSIDE THE STAFF AGREEMENT FOR STAKEHOLDER FEEDBACK

Subtitle A—Chair Sanders Staff Proposal

SEC. 601. BARDA REASONABLE PRICING REQUIREMENTS.

Section 319L(c)(5) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)) is amended by adding at the end the following:

''(I) REASONABLE PRICING.—

''(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into licenses or other transactions, under this section, the Secretary shall include terms and conditions

requiring that the price of a qualified countermeasure, qualified pandemic or epidemic product, security countermeasure, or related technology developed with support under this section is fair and reasonable for purposes of procurement by the Federal Government or if sold on the commercial market, taking into account the following factors:

''(I) The value of the countermeasure, product, or technology to the public health, including the impact of the price on access to the countermeasure, product, or technology.

''(II) The costs incurred by the Federal Government in research and development of the countermeasure, product, or technology.

''(III) The costs incurred by the person in research and development of the countermeasure, product, or technology, and the costs of manufacturing such countermeasure, product, or technology.

''(IV) Whether the countermeasure, product, or technology provided a significant improvement in health outcomes, compared to other therapies available at the time of its approval or authorization.

''(V) The cumulative expected global revenues generated by the countermeasure, product, or technology.

''(VI) Other factors, as the Secretary determines appropriate.

''(ii) MOST FAVORED NATION.—The Secretary shall include in any contract, grant, cooperative agreement, license, or other transaction under this section terms and conditions requiring that the price of a qualified countermeasure, qualified pandemic or epidemic product, security countermeasure, or related technology developed with support under this section and sold to the Federal Government or on the commercial market not exceed the lowest price charged for such countermeasure, product, or technology, among Canada,

France, Germany, Italy, Japan, and the United Kingdom.''.

SEC. 602. CDC REASONABLE PRICING REQUIREMENTS.

Section 305 of the Public Health Service Act (42 U.S.C. 242c) is amended by adding at the end the following:

''(f) REASONABLE PRICING.—

''(1) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into licenses or other transactions, related to the research and development of a covered product, the Director shall include terms and conditions requiring that the price of a covered product developed with support from the Centers for Disease Control and Prevention is fair and reasonable for purposes of procurement by the Federal Government or if sold on the commercial market, taking into account the following factors:

''(A) The value of the covered product to the public health, including the impact of the price on access to the covered product.

''(B) The costs incurred by the Federal Government in research and development of the covered product.

"(C) The costs incurred by the person in research and development of the covered product, and the costs of manufacturing such covered product.

"(D) Whether the covered product provided a significant improvement in health outcomes, compared to other therapies available at the time of its approval or authorization.

"(E) The cumulative expected global revenues generated by the covered product.

"(F) Other factors, as the Secretary determines appropriate.

"(2) MOST FAVORED NATION.—The Director shall include in any contract, grant, cooperative agreement, license, or other transaction terms and conditions requiring that the price of a covered product developed with support from the Centers for Disease Control and Prevention and sold to the Federal Government or on the commercial market not exceed the lowest price charged for such covered product, among Canada, France, Germany, Italy, Japan, and the United Kingdom.

"(3) DEFINITION.—For the purposes of this section, the term 'covered product' means—

''(A) a biological product (as defined in section 351(i));

''(B) a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act);

''(C) a device (as defined in section 201(h)(1) of such Act); or

''(D) another biomedical technology.''.

Subtitle B—Ranking Member Cassidy Staff Proposal

SEC. 611. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

Section 565A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended—

(1) in subsection (a)—

(A) in paragraph (3)—

(i) by inserting ''under subsection (b) or (c)'' after ''Secretary''; and

(ii) by inserting ''or military'' after ''material threat'' each place such term appears; and

(B) in paragraph (4)—

(i) in the paragraph heading, by inserting ''OR MILITARY'' after ''THREAT'';

(ii) in the matter preceding subparagraph (A), by inserting ''or military'' after ''threat'';

(iii) in subparagraph (A)—

(I) in clause (i), by striking ''; or'' and inserting a semicolon;

(II) by redesignating clause (ii) as clause (iii);

(III) by inserting after clause (i) the following:

''(ii) to prevent or treat harm from a biological, chemical, radiological, or nuclear agent that is determined by the Secretary of Defense to present a material threat against the Armed Forces sufficient to affect national security, other than any such agent that is identified as a material threat to the United States population as described in clause (i); or''; and

(IV) in clause (iii), as so redesignated, by striking ''such agent;'' and inserting ''an agent described in clause (i) or (ii);'';

(2) in subsection (b)—

(A) in the subsection heading, by inserting ''TRANSFERABLE'' before ''PRIORITY'';

(B) by inserting ''or military'' after ''material threat'' each place such term appears; and

(C) in paragraph (2)—

(i) in the first sentence, by striking ''this section'' and inserting ''this subsection''; and

(ii) in the second sentence, by inserting ''awarded under this subsection'' after ''review voucher'';

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

(4) by inserting after subsection (b) the following:

''(c) NON-TRANSFERABLE PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—In addition to the voucher awarded under subsection (b), the Secretary shall award another priority review voucher to the sponsor of a material threat or military medical countermeasure application upon approval by the Secretary of such material threat or military medical countermeasure application.

''(2) TRANSFERABILITY.—The sponsor of a material threat or military medical countermeasure application that receives a priority review voucher under this subsection may not transfer such voucher to any other person. Such a priority review voucher may only be used by the sponsor to whom the voucher is awarded.

''(3) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.'';

(5) in paragraph (1) of subsection (e), as so redesignated, by striking ''a priority review voucher under this section'' and inserting ''priority review vouchers under subsections (b) and (c)'';

(6) in subsection (f), as so redesignated, by inserting ''or military'' after ''material threat''; and

(7) in subsection (h), as so redesignated, by striking ''2023'' and inserting ''2028''.