Calendar No. 467

115TH CONGRESS
2D SESSION

S. 2852

To reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2018

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

JUNE 18, 2018

Reported by Mr. ALEXANDER, 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 Pandemic and All-Hazards Preparedness Reauthorization Act.

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 Advancing Innovation Act of 2018".~~

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

Sec. 1. Short title; table of contents.
Sec. 2. References in Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.
Sec. 202. Amendments to preparedness and response programs.
Sec. 203. Regional health care emergency preparedness and response systems.
Sec. 204. Public health and health care system situational awareness and biosurveillance capabilities.
Sec. 205. Strengthening and supporting the public health emergency rapid response fund.
Sec. 206. Improving preparedness for and response to all-hazards by public health emergency volunteers.

TITLE III—REACHING ALL COMMUNITIES

Sec. 301. Strengthening and assessing the emergency response workforce.
Sec. 302. Health system infrastructure to improve preparedness and response.
Sec. 303. Considerations for at-risk individuals.
Sec. 304. Improving emergency preparedness and response considerations for children.
Sec. 305. Reauthorizing the National Advisory Committee on Children and Disasters.
Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

Sec. 401. Assistant Secretary for Preparedness and Response.
Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
Sec. 403. Strategic National Stockpile.
Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.
Sec. 405. Reporting on the Federal Select Agent Program.

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

Sec. 501. Medical countermeasure budget plan.
Sec. 502. Material threat and medical countermeasure notifications.
Sec. 503. Availability of regulatory management plans.
Sec. 504. The Biomedical Advanced Research and Development Authority and the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

Sec. 601. Administration of countermeasures.
Sec. 602. Medical countermeasure master files.

Sec. 603. Animal rule report.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. Reauthorizations and extensions.
Sec. 702. Technical amendments.

SEC. 2. REFERENCES IN ACT.

Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''2014'' and inserting ''2018''; and

(ii) by striking the second sentence and inserting the following: ''Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with the national preparedness

goal (as described in section 504(a)(19) of the Homeland Security Act of 2002), the National Incident Management System (as defined in section 501(7) of such Act), and the National Response Plan developed pursuant to section 504 of such Act, or any successor plan.'';

(B) in paragraph (2), by inserting before the period at the end of the second sentence the following: '', and an analysis of any changes to the evidence-based benchmarks and objective standards under sections 319C–1 and 319C–2''; and

(C) in paragraph (3)—

(i) by striking ''2009'' and inserting ''2022'';

(ii) by inserting ''(including gaps in the environmental health workforce), describing the status of such workforce'' after ''gaps in such workforce'';

(iii) by striking ''and identifying strategies'' and inserting ''identifying strategies''; and

(iv) by inserting before the period at the end '', and identifying current capabili-

ties to meet the requirements of section 2803''; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''and investigation'' and inserting ''investigation, and related information technology activities'';

(ii) in subparagraph (B), by striking ''and decontamination'' and inserting ''decontamination, relevant health care services and supplies, and transportation and disposal of medical waste''; and

(iii) by adding at the end the following:

''(E) Response to environmental hazards.'';

(B) in paragraph (3)(F), by inserting ''or exposures to agents that could cause a public health emergency'' before the period;

(C) in paragraph (5), by inserting ''and other applicable compacts'' after ''Compact''; and

(D) by adding at the end the following:

''(9) ZOONOTIC DISEASE, FOOD, AND AGRICULTURE.—In consultation with the Secretary of

Agriculture, improving coordination among Federal, State, local, tribal, and territorial entities to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease) that could compromise national security resulting from a deliberate attack, a naturally occurring threat, the intentional adulteration of food, or other public health threats, taking into account interactions between animal health, human health, and animals' and humans' shared environment as directly related to public health emergency preparedness and response capabilities, as applicable.

''(10) GLOBAL HEALTH SECURITY.—Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.''.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR PREPAREDNESS AND RESPONSE.

(a) EVALUATING MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—Section 319C–1 (42 U.S.C. 247d–3a) is amended by inserting after subsection (j) the following:

''(k) EVALUATION.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

"(2) CONTENT.—The evaluation under this paragraph shall include—

"(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

"(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802;

"(C) a description of amounts received by eligible entities, as described in subsection (b) and section 319C–2(b), and amounts received by sub-recipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

"(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accurately assess the ability of entities receiving awards under this section to better achieve the goals under this section and section 2802.".

(b) EVALUATING THE PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–2(i)(1) (42 U.S.C. 247–3b(i)(1)) is amended by striking "section 319C–1(g), (i), and (j)" and inserting "section 319C–1(g), (i), (j), and (k)".

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS.

(a) COOPERATIVE AGREEMENT APPLICATIONS FOR IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Section 319C–1 (42 U.S.C. 247d–3a) is amended—

(1) in subsection (a), by inserting ", acting through the Director of the Centers for Disease Control and Prevention," after "the Secretary"; and

(2) in subsection (b)(2)(A)—

(A) in clause (vi), by inserting ", including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies," after "stakeholders";

(B) by redesignating clauses (vii) through (ix) as clauses (viii) through (x); and

(C) by inserting after clause (vi) the following:

"(vii) a description of how, as applicable, such entity may integrate information to account for individuals with behavioral health needs following a public health emergency;".

(b) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Section 319C–2 (42 U.S.C. 247d–3b) is amended—

(1) in subsection (a)—

(A) by inserting ", acting through the Assistant Secretary for Preparedness and Response," after "The Secretary"; and

(B) by striking ''preparedness for public health emergencies'' and inserting ''preparedness for, and response to, public health emergencies in accordance with subsection (c)''; and

(2) in subsection (b)(1)(A)—

(A) in clause (iii), by redesignating subclauses (I) through (III) as items (aa) through (cc), respectively, and adjusting the margins accordingly;

(B) by redesignating clauses (i) through (iii) as subclauses (I) through (III) respectively, and adjusting the margins accordingly;

(C) by striking ''partnership consisting of—'' and inserting ''partnership—

''(i) consisting of—''; and

(D) by adding at the end the following:

''(ii) that may include one or more emergency medical service organizations or emergency management organizations; and''.

(c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking ''$641,900,000 for fiscal year 2014'' and all that follows through the period at the end and inserting

"$685,000,000 for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5))."

(d) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is amended—

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

"(1) IN GENERAL.—

"(A) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 319C–3, in accordance with subparagraph (B), there is authorized to be appropriated $385,000,000 for each of fiscal years 2019 through 2023.

"(B) RESERVATIONS OF AMOUNTS FOR REGIONAL SYSTEMS.—

"(i) IN GENERAL.—Subject to clause (ii), of the amount appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve up to 5 percent for the purpose of carrying out section 319C–3.

''(ii) RESERVATIONS CONTINGENT ON CONTINUED APPROPRIATIONS.—If the amount appropriated under subparagraph (A) for fiscal year 2019 or a subsequent fiscal year is less than or equal the amount so appropriated for the previous fiscal year, the amount that may be reserved under clause (i) shall be reduced such that the amount remaining for the purpose of carrying out this section is not less than the amount available for such purpose for the previous fiscal year.'';

(2) in paragraph (2), by striking ''paragraph (1) for a fiscal year'' and inserting ''paragraph (1)(A) for a fiscal year and not reserved for the purpose described in paragraph (1)(B)(i)'', and

(3) in paragraph (3)(A), by striking ''paragraph (1) and not reserved under paragraph (2)'' and inserting ''paragraph (1)(A) and not reserved under paragraph (1)(B)(i) or (2)''.

SEC. 203. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

(a) IN GENERAL.—Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 319C–2 the following:

"SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

"(a) PURPOSE.—It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, and in advance of, a public health emergency, including threats posed by one or more chemical, biological, radiological, and nuclear agents, including emerging infectious diseases.

"(b) GUIDELINES.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, the Commissioner of Food and Drugs, the Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Affairs, heads of such other Federal agencies as the Secretary determines to be appropriate, and State, local, tribal, and territorial public health officials, shall, not later than 2 years after the date of enactment of this section—

"(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

"(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

"(i) the manner in which the system will coordinate with and integrate the partnerships established under section 319C–2(b); and

"(ii) informing and educating appropriate first responders and health care supply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such

hospitals and health care facilities in the community;

''(B) physical and technological infrastructure, laboratory capacity, staffing, blood supply, and other supply chain needs, taking into account resiliency, geographic considerations, and rural considerations;

''(C) protocols or best practices for the safety and personal protection of workers who handle human remains and health care workers (including with respect to protective equipment and supplies, waste management processes, and decontamination), sharing of specialized experience among the health care workforce, behavioral health, psychological resilience, and training of the workforce, as applicable;

''(D) in a manner that allows for disease containment (within the meaning of section 2802(b)(2)(B)), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

''(E) the needs of children and other at-risk individuals;

''(2) make such guidelines available on the internet website of the Department of Health and Human Services in a manner that does not compromise national security; and

''(3) update such guidelines as appropriate, including based on input received pursuant to subsections (c), (c), and (f), to address new and emerging public health threats.

''(c) CONSIDERATIONS.—In identifying, developing, and updating guidelines under subsection (b), the Assistant Secretary for Preparedness and Response shall—

''(1) include input from hospitals and health care facilities, including health care coalitions under section 319C–2, State, local, tribal, and territorial public health departments, and health care or subject matter experts, including experts with relevant expertise in chemical, biological, radiological, or nuclear threats, and emerging infectious disease as the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

''(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care fa-

cilities (including hospitals, primary care clinics, community health centers, mental health facilities, ambulatory care facilities, and dental health facilities), pharmacies, emergency medical providers, trauma care providers, environmental health agencies, public health laboratories, poison control centers, blood banks, and other experts that the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

''(3) consider feedback related to financial implications for hospitals, health care facilities, public health agencies, laboratories, and other entities engaged in regional preparedness planning to implement and follow such guidelines, as applicable; and

''(4) consider financial requirements and potential incentives for entities to prepare for, and respond to, public health emergencies as part of the regional health care emergency preparedness and response system.

''(d) TECHNICAL ASSISTANCE.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assist-

ance and consultation towards meeting the guidelines described in subsection (b).

''(c) DEMONSTRATION PROJECT FOR REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE SYSTEMS.—

''(1) IN GENERAL.—The Assistant Secretary for Preparedness and Response may establish a demonstration project pursuant to the development and implementation of guidelines under subsection (b) to improve medical surge capacity for all hazards, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, tribal, territorial, and regional jurisdictions.

''(2) SUNSET.—The authority under this subsection shall expire on September 30, 2023.

''(f) GAO REPORT TO CONGRESS.—

''(1) REPORT.—Not later than 3 years after the date of enactment of this section, the Comptroller General of the United States (referred to in this subsection as the 'Comptroller General') shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce

and the Committee on Ways and Means of the House of Representatives, a report on the extent to which hospitals and health care facilities have implemented the recommended guidelines under subsection (b), including an analysis and evaluation of any challenges hospitals or health care facilities experienced in implementing such guidelines.

"(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

"(A) data on the preparedness and response capabilities that have been informed by the guidelines under subsection (b) to improve regional emergency health care preparedness and response capability, including hospital and health care facility capacity and medical surge capabilities to prepare for, and respond to, public health emergencies; and

"(B) recommendations to reduce gaps in incentives for regional health partners, including hospitals and health care facilities to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a), which may include consideration of facilities participating in programs under section 319C–2, pro-

grams under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

''(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Comptroller General shall consult with the heads of appropriate Federal agencies, including—

''(A) the Assistant Secretary for Preparedness and Response;

''(B) the Director of the Centers for Disease Control and Prevention;

''(C) the Administrator of the Centers for Medicare & Medicaid Services;

''(D) the Assistant Secretary for Mental Health and Substance Use;

''(E) the Assistant Secretary of Labor for Occupational Safety and Health;

''(F) the Secretary of Veterans Affairs; and

''(G) the heads of such other Federal agencies as the Secretary determines appropriate.''.

(b) ANNUAL REPORTS.—Section 319C–2(i)(1) (42 U.S.C. 247d–3b(i)(1)) is amended by inserting after the first sentence the following ''The reports submitted under

this paragraph shall also include progress towards the implementation of section 319C–3.''.

(c) NATIONAL HEALTH SECURITY STRATEGY INCORPORATION OF REGIONALIZED EMERGENCY PREPAREDNESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended—

(1) in the matter preceding subparagraph (A), by striking ''including mental health'' and inserting ''including pharmacies, mental health facilities,''; and

(2) by amending subparagraph (G) to read as follows:

''(G) Optimizing a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems, which may include the implementation of guidelines for regional health care emergency preparedness and response systems under section 319C–3.''.

(d) IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—

(1) STATE AND LOCAL SECURITY.—Section 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by

striking ", and local emergency plans." and inserting ", local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.".

(2) PARTNERSHIPS.—Section 319C–2(d)(1)(A) (42 U.S.C. 247d–3b(d)(1)(A)) is amended—

(A) in clause (i), by striking "; and" and inserting ";";

(B) by redesignating clause (ii) as clause (iii); and

(C) inserting after clause (i), the following:

"(ii) among one or more facilities in a regional health care emergency system under section 319C–3; and".

SEC. 204. PUBLIC HEALTH AND HEALTH CARE SYSTEM SITUATIONAL AWARENESS AND BIOSURVEILLANCE CAPABILITIES.

(a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE CAPABILITIES.—Section 319D (42 U.S.C. 247d–4) is amended—

(1) in the section heading, by striking "**REVITALIZING**" and inserting "**FACILITIES AND CAPACITIES OF**";

(2) in subsection (a)—

(A) in the subsection heading, by striking ''FACILITIES; CAPACITIES'' and inserting ''IN GENERAL'';

(B) in paragraph (1), by striking ''and improved'' and inserting '', improved, and appropriately maintained'';

(C) in paragraph (3), in the matter preceding subparagraph (A), by striking ''expand, enhance, and improve'' and inserting ''expand, improve, enhance, and appropriately maintain''; and

(D) by adding at the end the following:

''(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years 2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations

and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.'';

(3) in subsection (b)—

(A) in the subsection heading, by striking ''NATIONAL'' and inserting ''ESTABLISHMENT OF SYSTEMS OF PUBLIC HEALTH '';

(B) in paragraph (1)(B), by inserting ''immunization information systems,'' after ''centers,'';

(C) in paragraph (2)—

(i) by inserting ''develop a plan to, and'' after ''The Secretary shall''; and

(ii) by inserting ''and in a form readily usable for analytical approaches'' after ''in a secure manner''; and

(D) by amending paragraph (3) to read as follows:

''(3) STANDARDS.—

''(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary,

in cooperation with health care providers, State, local, tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

"(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.";

(4) in subsection (c)—

(A) in paragraph (1)—

(i) by striking ''Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary'' and inserting ''The Secretary'';

(ii) by inserting '', and improve as applicable and appropriate,'' after ''shall establish'';

(iii) by striking ''of rapid'' and inserting ''of, rapid''; and

(iv) by striking ''such connectivity'' and inserting ''such interoperability'';

(B) by amending paragraph (2) to read as follows:

''(2) COORDINATION AND CONSULTATION.—In establishing and improving the network under paragraph (1) the Secretary shall—

''(A) facilitate coordination among agencies within the Department of Health and Human Services that provide or have the potential to provide information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health

information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

''(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, and the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.'';

(C) in paragraph (3)—

(i) by redesignating subparagraphs (A) through (E) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (iv), as so redesignated—

(I) by inserting ''immunization information programs,'' after ''poison control,''; and

(II) by striking ''and clinical laboratories'' and inserting '', clinical

laboratories, and public environmental health agencies'';

(iii) by striking ''The network'' and inserting the following:

''(A) IN GENERAL.—The network''; and

(iv) by adding at the end the following:

''(B) REVIEW.—Not later than 2 years after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such review shall include a discussion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.'';

(D) in paragraph (5)—

(i) by redesignating subparagraphs (A) through (D) as clauses (i) through

(iv), respectively, and adjusting the margins accordingly;

(ii) by striking ''In establishing'' and inserting the following:

''(A) IN GENERAL.—In establishing'';

(iii) by adding at the end the following:

''(B) PUBLIC MEETING.—

''(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

''(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards

and Technology), State, local, tribal, and territorial public health officials, stakeholders with expertise in biosurveillance and situational awareness, and stakeholders with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction and forecasting), and other representatives as the Secretary determines appropriate.

''(iii) TOPICS.—Such public meeting shall include a discussion of—

''(I) data elements, including minimal or essential data elements, that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

''(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

''(III) strategies to encourage the access, exchange, and use of information;

''(IV) considerations for State, local, tribal, and territorial capabilities and infrastructure related to data exchange and interoperability;

''(V) privacy and security protections provided at the Federal, State, local, tribal, and territorial levels, and by nongovernmental stakeholders; and

''(VI) opportunities for the incorporation of innovative technologies to improve the network.''; and

(iv) in subparagraph (A), as so designated by clause (ii)—

(I) in clause (i), as so redesignated—

(aa) by striking ''as determined'' and inserting ''as adopted''; and

(bb) by inserting ''and the National Institute of Standards and Technology'' after ''Office of

the National Coordinator for Health Information Technology'';

(II) in clause (iii), as so redesignated, by striking ''; and'' and inserting a semicolon;

(III) in clause (iv), as so redesignated, by striking the period and inserting ''; and''; and

(IV) by adding at the end the following:

''(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, tribal, and territorial public health entities may utilize, on a voluntary basis, as a part of the network.'';

(E) by redesignating paragraph (6) as paragraph (7);

(F) by inserting after paragraph (5) the following:

''(6) STRATEGY AND IMPLEMENTATION PLAN.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Pan-

demic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall submit to the appropriate committees of Congress a coordinated strategy and an accompanying implementation plan that—

"(i) is informed by the public meeting under paragraph (5)(B);

"(ii) includes a review and assessment of existing capabilities of the network and related infrastructure, including input provided by the public meeting under paragraph (5)(B);

"(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

"(I) develop, implement, and evaluate the network described in paragraph (1), utilizing elements described in paragraph (3)(A);

"(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting

for pandemics and all-hazards) from public and private entities;

''(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies; and

''(IV) test and evaluate capabilities of the interoperable network of systems to improve situational awareness and biosurveillance capabilities;

''(iv) includes performance measures and the metrics by which performance measures will be assessed with respect to the measurable steps under clause (iii); and

''(v) establishes dates by which each measurable step under clause (iii) will be implemented.''.

"(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

"(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

"(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

"(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance ca-

pabilities, resources, and authorities needed to address such gaps; and

''(iv) a strategy to minimize and address such gaps and improve inefficiencies.'';

(G) in paragraph (7), as so redesignated—

(i) in subparagraph (A), by inserting ''(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)'' after ''human health'';

(ii) in subparagraph (B)—

(I) by inserting ''and gaps in surveillance programs'' after ''surveillance programs''; and

(II) by striking ''; and'' and inserting a semicolon;

(iii) in subparagraph (C)—

(I) by inserting '', animal health organizations related to zoonotic disease,'' after ''health care entities''; and

(II) by striking the period and inserting ''; and''; and

(iv) by adding at the end the following:

"(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 2802."; and

(H) by adding at the end the following:

"(8) SITUATIONAL AWARENESS AND BIOSURVEILLANCE AS A NATIONAL SECURITY PRIORITY.—The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development and capabilities of the nationwide public health situational awareness and biosurveillance network.";

(5) in subsection (d)—

(A) in paragraph (1)—

(i) by inserting "environmental health agencies," after "public health agencies,"; and

(ii) by inserting "immunization programs," after "poison control centers,"; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking "and" at the end;

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

(iii) by adding after subparagraph (C) the following:

''(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1).''; and

(C) by striking paragraph (5) and inserting the following:

''(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, tribes, and territories or a consortium of States, localities, tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.'';

(6) by redesignating subsections (f) and (g) as subsections (h) and (i), respectively; and

(7) by inserting after subsection (e) the following:

''(f) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to Congress for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

''(g) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (h) of section 319D (42 U.S.C. 247d–4), as redesignated by subsection (a)(6), is amended by striking ''$138,300,000 for each of fiscal years 2014 through 2018'' and inserting ''$161,800,000 for each of fiscal years 2019 through 2023''.

SEC. 205. STRENGTHENING AND SUPPORTING THE PUBLIC HEALTH EMERGENCY RAPID RESPONSE FUND.

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

(1) in subsection (b)—

(A) in paragraph (1)—

(i) in the first sentence, by inserting ''or if the Secretary determines there is the

significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency'' before the period; and

(ii) by inserting ''The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities.'' after the first sentence;

(B) by redesignating paragraph (2) as paragraph (3);

(C) by inserting after paragraph (1) the following:

''(2) USES.—The Secretary may use amounts in the Fund established under paragraph (1), to—

''(A) facilitate coordination between and among Federal, State, local, tribal, and territorial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency (including communication of such entities with relevant international entities, as applicable);

"(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 319C–1 or 319C–2;

"(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

"(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information on such public health emergency or potential public health emergency, including the systems under section 319D;

"(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel expenses under section 2812, and the Medical Reserve Corps under section 2813; and

"(F) other activities, as the Secretary determines applicable and appropriate."; and

(D) by inserting after paragraph (3), as so redesignated, the following:

"(4) REVIEW.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section, and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

"(5) GAO REPORT.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct a review of the Fund under this section, including the uses and the resources available in the Fund."; and

(2) in subsection (c)—

(A) by inserting ''rapidly respond to public health emergencies or potential public health emergencies and'' after ''used to''; and

(B) by striking ''section.'' and inserting ''Act or funds otherwise provided for emergency response.''.

SEC. 206. IMPROVING PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS BY PUBLIC HEALTH EMERGENCY VOLUNTEERS.

Section 319I (42 U.S.C. 247d–7b) is amended:

(1) in subsection (a), by adding at the end the following: ''Such health care professionals may include members of the National Disaster Medical System, members of the Medical Reserve Corps, and individual health care professionals.'';

(2) in subsection (i) by adding at the end ''In order to inform the development of such mechanisms by States, the Secretary shall make available information and material provided by States that have developed mechanisms to waive the application of licensing requirements to applicable health professionals seeking to provide medical services during a public health emergency. Such information shall be made publicly available in a manner that does not jeopardize national security.''; and

(3) in subsection (k) by striking ''$2014 through 2018'' and inserting ''2019 through 2023''.

TITLE III—REACHING ALL COMMUNITIES

SEC. 301. STRENGTHENING AND ASSESSING THE EMERGENCY RESPONSE WORKFORCE.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause (ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh–11(a)(3)(A)) is amended to read as follows:

''(ii) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified, or there is a significant potential for a public health emergency.''.

(b) VOLUNTEER MEDICAL RESERVE CORPS.—Section 2813(a) (42 U.S.C. 42 U.S.C. 300hh–15(a)) is amended by striking the second sentence and inserting ''The Secretary may appoint a Director to head the Corps and oversee the activities of the Corps chapters that exist at the State, local, and tribal levels.''

(c) REVIEW OF THE NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh–11(b)(2)) is amended to read as follows:

"(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—

"(A) REVIEW.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include—

"(i) an evaluation of medical surge capacity, as described in section 2803(a);

"(ii) an assessment of the available workforce of the intermittent disaster response personnel described in subsection (c);

"(iii) the capacity of the workforce described in clause (ii) to respond to all hazards, including capacity to simultaneously respond to multiple public health emergencies and the capacity to respond to a nationwide public health emergency;

"(iv) the effectiveness of efforts to recruit, retain, and train such workforce; and

''(v) gaps that may exist in such workforce and recommendations for addressing such gaps.

''(B) UPDATES.—As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from the review under subparagraph (A) and provide recommendations to modify the policies of the National Disaster Medical System as necessary.''.

(d) NOTIFICATION OF NDMS SHORTAGE.—Section 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding at the end the following:

''(3) SERVICE BENEFIT.—Individuals appointed to serve under this subsection shall be considered public safety officers under part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968. The Secretary shall provide notification to eligible individuals of any effect such designation may have on other benefits for which such individuals are eligible, including benefits from private entities.

''(4) NOTIFICATION.—Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster response personnel of such System is insufficient to address a public health emergency or potential public health emer-

gency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency, and any identified measures to address such shortage.

"(5) CERTAIN APPOINTMENTS.—

"(A) IN GENERAL.—If the Secretary determines that the number of intermittent disaster response personnel within the National Disaster Medical System under this section is insufficient to address a public health emergency or potential public health emergency, the Secretary may appoint candidates directly to personnel positions for intermittent disaster response within such system. The Secretary shall provide updates on the number of vacant or unfilled positions within such system to the congressional committees of jurisdiction each quarter for which this authority is in effect.

"(B) SUNSET.—The authority under this paragraph shall expire on September 30, 2021.".

(c) PUBLIC SAFETY OFFICER BENEFITS.—Section 1204(9) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

(1) in subparagraph (C)(ii), by striking ''or'' at the end;

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

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

''(E) an individual appointed to the National Disaster Medical System under section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) who is performing official duties of the Department of Health and Human Services, if those official duties are related to responding to a public health emergency or potential public health emergency, or other activities for which the Secretary of Health and Human Services has activated such National Disaster Medical System.''.

(f) NATIONAL DISASTER MEDICAL SYSTEM AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) (42 U.S.C. 300hh–11(g)) is amended by striking ''$52,700,000 for each of fiscal years 2014 through 2018''

and inserting ''$57,400,000 for each of fiscal years 2019 through 2023''.

(g) MEDICAL RESERVE CORPS AUTHORIZATION OF APPROPRIATIONS.—Section 2813(i) (42 U.S.C. 300hh–15(i)) is amended by striking ''2014 through 2018'' and inserting ''2019 through 2023''.

SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE PREPAREDNESS AND RESPONSE.

(a) COORDINATION OF PREPAREDNESS.—Section 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by adding at the end the following: ''Such logistical support shall include working with other relevant Federal, State, local, tribal, and territorial public health officials and private sector partners to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including an emergency under section 319, an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed

or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.''.

(b) MANUFACTURING CAPACITY.—Section 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting '', and ancillary medical supplies to assist with the utilization of such products,'' after ''products''.

SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.

(a) AT-RISK INDIVIDUALS IN THE NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B) (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

(1) by striking ''this section and sections 319C–1, 319F, and 319L,'' and inserting ''this Act''; and

(2) by striking ''special'' and inserting ''access or functional''.

(b) COUNTERMEASURE CONSIDERATIONS.—Section 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

(1) by striking ''elderly'' and inserting ''senior citizens''; and

(2) by inserting ''with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products'' before the period.

SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND RESPONSE CONSIDERATIONS FOR CHILDREN.

Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 319D the following:

"SEC. 319D–1. CHILDREN'S PREPAREDNESS UNIT.

"(a) ENHANCING EMERGENCY PREPAREDNESS FOR CHILDREN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this subsection as the 'Director'), shall maintain an internal team of experts, to be known as the Children's Preparedness Unit (referred to in this subsection as the 'Unit'), to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Unit shall inform the Director regarding emergency preparedness and response efforts pertaining to children at the Centers for Disease Control and Prevention.

"(b) EXPERTISE.—The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavior pediatrician, and may also include behavioral scientists, child psychologists, epidemiologists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

"(c) DUTIES.—The team described in subsection (a) may—

"(1) assist State, local, tribal, and territorial emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

"(2) provide technical assistance, training, and consultation to Federal, State, local, tribal, and territorial public health officials to improve preparedness and response capabilities with respect to the needs of children, including providing such technical assistance, training, and consultation to eligible entities in order to support the achievement of measurable evidence-based benchmarks and objective standards applicable to sections 319C–1 and 319C–2;

"(3) improve the utilization of methods to incorporate the needs of children in planning for and responding to a public health emergency, including public awareness of such methods;

"(4) coordinate with, and improve, public-private partnerships, such as health care coalitions pursuant to sections 319C–2 and 319C–3, to address gaps and inefficiencies in emergency preparedness and response efforts for children;

''(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies; and

''(6) carry out other duties related to preparedness and response activities for children, as the Secretary determines appropriate.''.

SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

Section 2811A (42 U.S.C. 300hh–10a) is amended—

(1) in subsection (b)(2), by inserting '', mental and behavioral,'' after ''medical'';

(2) in subsection (d)—

(A) in paragraph (1), by striking ''15'' and inserting ''25''; and

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

''(2) REQUIRED NON-FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals to perform the duties described in subsections (b) and (c), including—

"(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

"(B) at least 2 representatives from State, local, tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

"(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine, pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents and emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

"(D) other members as the Secretary determines appropriate, of whom—

"(i) at least one such member shall represent a children's hospital;

"(ii) at least one such member shall be an individual with expertise in schools or child care settings;

~~"(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and~~

~~"(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities.".~~

~~"(3) FEDERAL MEMBERS.—The Advisory Committee under paragraph (1) shall include the following Federal members or their designees:~~

~~"(A) The Assistant Secretary for Preparedness and Response.~~

~~"(B) The Director of the Biomedical Advanced Research and Development Authority.~~

~~"(C) The Director of the Centers for Disease Control and Prevention.~~

~~"(D) The Commissioner of Food and Drugs.~~

~~"(E) The Director of the National Institutes of Health.~~

~~"(F) The Assistant Secretary of the Administration for Children and Families.~~

"(G) The Administrator of the Health Resources and Services Administration.

"(H) The Administrator of the Federal Emergency Management Agency.

"(I) The Administrator of the Administration for Community Living.

"(J) The Secretary of Education.

"(K) Representatives from such Federal agencies (such as the Substance Abuse and Mental Health Services Administration and the Department of Homeland Security) as the Secretary determines appropriate to fulfill the duties of the Advisory Committee under subsections (b) and (c).".

"(4) TERM OF APPOINTMENT.—Each member of the Advisory Committee appointed under paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the Advisory Committee appointees serving on the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, or appointees who are initially appointed after such date of enactment, in order to provide for a staggered term of appointment for all members.

''(5) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member appointed under paragraph (2) may serve not more than 3 terms on the Advisory Committee, and not more than 2 of which may be served consecutively.'';

(3) in subsection (e), by adding at the end ''At least one meeting per year shall be an in-person meeting.''; and

(4) in subsection (f) by striking ''2018'' and inserting ''2023''.

SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES AND DRILLS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance regarding the participation of State, local, tribal, and territorial public health department or agency personnel funded in whole or in part through programs authorized under this Act in drills and operational exercises in order to identify, inform, and address the gaps in and policies related to all-hazards medical and public health preparedness and response, which may include drills and operational exercises that incorporate medical surge capacity planning, medical countermeasure distribution and administration, and preparing for and responding to identified threats for that region.

The Secretary shall consult with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies as necessary and appropriate in the development of such guidance. The Secretary shall make the guidance available on the internet website of the Department of Health and Human Services.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811(b) (42 U.S.C. 300hh–10(b)) is amended—

(1) in the matter preceding paragraph (1) by inserting "utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to" after "shall"; and

(2) in paragraph (4) by adding at the end the following:

"(I) THREAT AWARENESS.—Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for Na-

tional Security Affairs, the Secretary of Defense, and other relevant Federal officials, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.''.

SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

(a) IN GENERAL.—Title XXVIII is amended by inserting after section 2811 (42 U.S.C. 300hh–10) the following:

''SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

''(a) IN GENERAL.—The Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the 'PHEMCE'). The Assistant Secretary for Preparedness and Response shall serve as chair of the PHEMCE.

''(b) MEMBERS.—The PHEMCE shall include each of the following members, or the designee of such members:

''(1) The Assistant Secretary for Preparedness and Response.

~~"(2) The Director of the Centers for Disease Control and Prevention.~~

~~"(3) The Director of the National Institutes of Health.~~

~~"(4) The Commissioner of Food and Drugs.~~

~~"(5) The Secretary of Defense.~~

~~"(6) The Secretary of Homeland Security.~~

~~"(7) The Secretary of Agriculture.~~

~~"(8) The Secretary of Veterans Affairs.~~

~~"(9) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, and the Director of the Strategic National Stockpile, as the Secretary determines appropriate.~~

~~"(c) FUNCTIONS.—~~

~~"(1) IN GENERAL.—The functions of the PHEMCE shall include the following:~~

~~"(A) Establish a process pursuant to section 2811(d)(2)(B) to make recommendations to the Secretary regarding the prioritization of research, development, and procurement of countermeasures, as defined in section 319F–2(c), based on the health security needs of the United States. Such recommendations shall be informed by the National Health Security~~

Strategy pursuant to section 2802, the Strategic National Stockpile review required under section 319F–2(a)(2), the countermeasures budget plan pursuant to section 2811(b)(7), and an assessment of current national security threats, including chemical, biological, radiological and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

"(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures and challenges to addressing such needs (including any regulatory challenges), and provide for alignment of countermeasure procurement with recommendations under subparagraph (A).

"(C) Develop strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 319F–2(a).

"(D) Provide consultation for the development of the strategy and implementation plan under section 2811(d).

"(2) INPUT.—In carrying out subparagraphs (B) and (C) of paragraph (1), the PHEMCE shall solicit and consider input from State, local, tribal, and territorial public health departments, as appropriate.".

(b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—Section 2811(d)(1) (42 U.S.C. 300hh–10(d)(1)) is amended—

(1) by striking "Not later than 180 days after the date of enactment of this subsection, and every year thereafter" and inserting "Not later than March 15, 2020, and biennially thereafter"; and

(2) by striking "Director of Biomedical" and all that follows through "Food and Drugs" and inserting "Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1".

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

(a) Section 319F–2(a) (42 U.S.C. 247d–6b(a)) is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) in paragraph (1)—

(A) by inserting "and optimize" after "provide for";

(B) by inserting "and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 2811–1, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2)" before the period of the first sentence; and

(C) by striking the second sentence;

(3) by inserting after paragraph (1) the following:

"(2) THREAT-BASED REVIEW.—

"(A) IN GENERAL.—The Secretary shall conduct a biennial threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under

section 2811–1, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review shall be submitted biennially, beginning on March 15, 2019, 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, in a manner that does not compromise national security.

"(B) ADDITIONS, MODIFICATIONS, AND REPLENISHMENTS.—Each biennial threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

"(i) information regarding—

"(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

"(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of

such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;

"(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

"(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

"(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emer-

gency preparedness to address such threats;

''(VI) whether such countermeasure is replenishing an expired countermeasure, is a different countermeasure with the same indication that is replacing an expired countermeasure, or is a new addition to the stockpile;

''(VII) a description of how such additions or modifications align with the countermeasures budget plan as required under section 2811(b)(7), including expected life-cycle costs, expenditures related to countermeasure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

''(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the counter-

measure at the State and local level, including plans for relevant capabilities of State and local entities to dispense, distribute, and administer the countermeasure; and

''(ii) an assurance that for each countermeasure produced or replenished under this subsection, the Secretary completed a review addressing each item listed under this subsection in advance of such procurement or replenishment, which need not be provided in advance of procurement.'';

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

(A) in subparagraph (A), by inserting ''and the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1'' before the semicolon;

(B) in subparagraph (C), by inserting '', and the availability, deployment, dispensing, and administration of countermeasures'' before the semicolon; and

(C) by amending subparagraph (E) to read as follows:

''(E) devise plans for effective and timely supply-chain management of the stockpile, in

consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies, State, local, tribal, and territorial agencies, and the public and private health care infrastructure, as applicable, taking into account the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile''; and

(5) by adding at the end the following:

''(5) GAO REPORT.—

''(A) IN GENERAL.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

‘‘(i) an assessment of the comprehensiveness and completeness of each biennial threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

‘‘(ii) an assessment of whether the Secretary established health security and science-based justifications, and a description of such justifications for procurement decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

‘‘(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of coun-

termeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

''(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

''(v) an analysis of how such procurement decisions made progress towards meeting emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

''(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the emergency health security needs of the stockpile;

"(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General; and

"(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities.

"(B) SUBMISSION.—Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an unclassified version of the review to the appropriate committees of Congress.".

(b) AUTHORIZATION OF APPROPRIATIONS, STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42 U.S.C. 247d–6b(f)(1)) is amended by striking

~~"$533,800,000 for each of fiscal years 2014 through 2018" and inserting "$610,000,000 for each of fiscal years 2019 through 2023".~~

~~SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTIMICROBIAL RESISTANCE, AND OTHER SIGNIFICANT THREATS.~~

~~Section 319L(c)(4) (247d–7e(c)(4)) is amended by adding at the end the following:~~

~~"(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs, supporting innovative candidate products in preclinical and clinical development, to address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, counter-~~

measures and products, as applicable, to address areas including—

"(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

"(ii) threats that consistently exist or continually circulate and have significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, 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); and

''(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.''.

SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT PROGRAM.

Section 351A(k) (42 U.S.C. 262a) is amended—

(1) by striking ''The Secretary'' and inserting the following:

''(1) IN GENERAL.—The Secretary''; and

(2) by adding at the end the following:

''(2) IMPLEMENTATION OF RECOMMENDATIONS OF THE FEDERAL EXPERTS SECURITY ADVISORY PANEL AND THE FAST TRACK ACTION COMMITTEE ON SELECT AGENT REGULATIONS.—

''(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Ad-

vancing Innovation Act of 2018, the Secretary shall provide an update to the appropriate committees of Congress on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

''(B) CONTINUED UPDATES.—The Secretary shall provide status updates at 6-month intervals following the submission of the update under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.''.

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking ''March 1 of each year'' and inserting ''March 15, 2020 and every 2 years thereafter'';

(2) by striking subparagraph (A) and inserting the following:

"(A) include consideration of the entire medical countermeasures enterprise, including—

"(i) basic research and advanced research and development;

"(ii) approval, clearance, licensure, and authorized uses of products;

"(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile; and

"(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development;".

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

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

"(D) identify the full range of anticipated medical countermeasure needs related to re-

search and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;''; and

(5) in subparagraph (E), as so redesignated, by striking ''March 15 of each year'' and inserting ''March 15, 2020, and every 2 years thereafter''.

SEC. 502. MATERIAL THREAT AND MEDICAL COUNTERMEASURE NOTIFICATIONS.

(a) CONGRESSIONAL NOTIFICATION OF MATERIAL THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42 U.S.C. 247d–6b(c)(2)(C)) is amended by striking ''The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress'' and inserting ''The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Government Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives''.

(b) CONTRACTING COMMUNICATIONS.—

(1) CONTRACT DURATION.—Section 319F–2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–6b(c)(7)(B)(ii)(III)) is amended by adding at the end the following: ''The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew such contract.''.

(2) EXPEDITED AUTHORITIES.—Section 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is amended by adding at the end the following: ''Upon award, extension, or termination of any such contract, grant, cooperative agreement, and other transaction, the Secretary shall provide a written notification to the receiving entity that includes a justification for such award, extension, or termination.''.

SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT PLANS.

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

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

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

''(3) PUBLICATION.—The Secretary shall make available on the internet website of the Food and

Drug Administration information regarding regulatory management plans, including—

"(A) the process by which an applicant may submit a request for a regulatory management plan;

"(B) the timeframe by which the Secretary is required to respond to such request;

"(C) the information required for the submission of such request;

"(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

"(E) contact information for beginning the regulatory management plan process.";

(3) in paragraph (6), as so redesignated, in the matter preceding subparagraph (A)—

(A) by striking "paragraph (4)(A)" and inserting "paragraph (5)(A)"; and

(B) by striking "paragraph (4)(B)" and inserting "paragraph (5)(B)"; and

(4) in paragraph (7)(A), as so redesignated, by striking "paragraph (3)(A)" and inserting "paragraph (4)(A)".

SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY AND THE BIOSHIELD SPECIAL RESERVE FUND.

(a) BIOSHIELD SPECIAL RESERVE FUND.—Section 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

(1) by striking ''$2,800,000,000 for the period of fiscal years 2014 through 2018'' and inserting ''$3,500,000,000 for the period of fiscal years 2019 through 2023, to remain available until expended''; and

(2) by striking the second sentence.

(b) THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42 U.S.C. 247d–7e(d)(2)) is amended by striking ''$415,000,000 for each of fiscal years 2014 through 2018'' and inserting ''$611,700,000 for each of fiscal years 2019 through 2023''.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

SEC. 601. ADMINISTRATION OF COUNTERMEASURES.

Section 319L(e)(4)(D)(iii) (42 U.S.C. 247d–7e(e)(4)(D)(iii)) is amended by striking ''and platform technologies'' inserting ''platform technologies, technologies to administer countermeasures, technologies to improve storage, and transportation of countermeasures''.

SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 565A the following:

"SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

"(a) PURPOSE.—The purpose of this section is to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encouraging submission of data and information to support such products to master files, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary.

"(b) APPLICABILITY OF REFERENCE.—

"(1) IN GENERAL.—A person may submit data and information to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information, in accordance with subsections (d) and (e) of section 314.420 of title 21, Code of Federal Regulations (or any successor regulations), to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to refcerence the master file.

''(2) MASTER FILE HOLDER.—In this section, the term 'master file holder' means a person who submits data and information to the Secretary with the intent to reference or authorize to reference such data or information to support a medical countermeasure submission, as described in paragraph (1).

''(c) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

''(1) IN GENERAL.—A master file under this section may include information to support and accelerate—

''(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

''(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

''(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are up-

dated during the time such master file is referenced for a medical countermeasure submission.

''(d) SPONSOR REFERENCE.—

''(1) IN GENERAL.—Each incorporation of information or data contained in a master file by reference shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such information without necessitating resubmission of such information or data. Master files shall be submitted in an electronic format in accordance with section 745A and as specified in applicable guidance.

''(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

''(3) REFERENCE BY AN AUTHORIZED PERSON.—A sponsor of a medical countermeasure submission may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

"(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE SECRETARY.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified information or data within a master file and the purposes for which such information or data was incorporated by reference if the Secretary has reviewed and relied upon such specified information or data to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

"(f) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the authority of the Secretary to approve, license, classify, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the Pandemic and All-Hazards Pre-

paredness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act; or

"(2) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of information or data previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 505(i), 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

"(g) DEFINITIONS.—In this section:

"(1) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biological product license application under section 351(k)

of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or request for an emergency use authorization under section 564 to support—

"(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

"(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

"(2) The terms 'qualified countermeasure', 'security countermeasure', and 'qualified pandemic or epidemic product' have the meanings given such terms in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act.".

(b) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through the reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) GUIDANCE.—Not later than 2 years after the after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master

files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

SEC. 603. ANIMAL RULE REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the application of the requirements under section 565(d) of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d)) (referred to in this section as the "animal rule") as a component of medical countermeasure advanced development under the Biomedical Advanced Research and Development Authority and regulatory review by the Food and Drug Administration. In conducting such study, the Comptroller General shall examine the following:

(1) The extent to which advanced development and review of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug

~~Administration, including activities facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal rule, consistent with the recommendations in the animal rule guidance, issued pursuant to section 565(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled "Product Development Under the Animal Rule Guidance for Industry" (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.~~

~~(2) The consistency of the application of the animal rule among and between review divisions within the Food and Drug Administration.~~

~~(3) The flexibilities pursuant to the animal rule to address variations in countermeasure development and review processes, including the extent to which qualified animal models are adopted and used within the Food and Drug Administration in regulatory decisionmaking with respect to medical countermeasures.~~

(4) The extent to which the guidance issued under section 565(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled, ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October 2015), has assisted in achieving the purposes described in paragraphs (1), (2), and (3).

(b) CONSULTATIONS.—In conducting the study under subsection (a), the Comptroller General of the United States shall consult with—

(1) the Federal agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Department of Defense;

(2) manufacturers involved in the research and development of medical countermeasures to address biological, chemical, radiological, and nuclear threats; and

(3) other biodefense stakeholders, as applicable.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health,

Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a) and recommendations to improve the application and consistency of the requirements under subsections (c) and (d) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this section in a manner that does not compromise national security.

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

(a) VETERANS AFFAIRS.—Section 8117(g) of title 38, United States Code, is amended by striking ''2014 through 2018'' and inserting ''2019 through 2023''.

(b) VACCINE TRACKING AND DISTRIBUTION.—Section 319A(e) (42 U.S.C. 247d–1(e)) is amended by striking ''2014 through 2018'' and inserting ''2019 through 2023''.

(c) TEMPORARY REASSIGNMENT.—Section 319(e)(8) (42 U.S.C. 247d(e)(8)) is amended by striking ''2018'' and inserting ''2023''.

(d) STRATEGIC INNOVATION PARTNER.—Section 319L(e)(4)(E)(ix) (42 U.S.C. 247d–7e(e)(4)(E)(ix)) is amended by striking ''2022'' and inserting ''2023''.

(e) PUBLIC DISCLOSURE EXEMPTION.—Section 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking ''12'' and inserting ''17''.

(f) LIMITED ANTITRUST EXEMPTION.—

(1) IN GENERAL.—Section 405 of the Pandemic and All-Hazards Preparedness Act (42 U.S.C. 247d–6a note) is amended—

(A) by redesignating such section as section 319L–1;

(B) transferring such section to the Public Health Service Act (42 U.S.C. 201 et seq.), to appear after section 319L of such Act (42 U.S.C. 247d–7e);

(C) in subsection (a)(1)—

(i) by striking ''Secretary of Health and Human Services (referred to in this subsection as the 'Secretary')'' and inserting ''Secretary'';

(ii) by striking ''of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act'';

(iii) by striking ''of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act''; and

(iv) by striking ''of the Public Health Service Act (42 U.S.C. 247d–6d)''; and

(D) in subsection (b), by striking ''12-year'' and inserting ''17-year''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1)(D) shall take effect as if enacted on December 17, 2012.

(3) CONFORMING AMENDMENT.—The table of contents in section 1(b) of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) is amended by striking the item related to section 405.

SEC. 702. TECHNICAL AMENDMENTS.

(a) PUBLIC HEALTH SERVICE ACT.—Title III (42 U.S.C. 241 et seq.) is amended—

(1) in paragraphs (1) and (5) of section 319F–1(a) (42 U.S.C. 247d–6a(a)), by striking ''section 319F(h)'' each place such term appears and inserting ''section 319F(e)''; and

~~(2) in section 319K(a) (42 U.S.C. 247d–7d(a)), by striking "section 319F(h)(4)" and inserting "section 319F(c)(4)".~~

~~(b) PUBLIC HEALTH SECURITY GRANTS.—Section 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—~~

~~(1) in subparagraph (C), by striking "individuals,," and inserting "individuals,"; and~~

~~(2) in subparagraph (F), by striking "make satisfactory annual improvement and describe" and inserting "makes satisfactory annual improvement and describes".~~

~~(c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—The Federal Food, Drug, and Cosmetic Act is amended—~~

~~(1) in section 564A(c)(2)(A) (21 U.S.C. 360bbb–3a(c)(2)(A)), by striking "subsection (a)(1)(C)(i)" and inserting "subsection (a)(1)(C)"; and~~

~~(2) in section 564B(2)(C) (21 U.S.C. 360bbb–3b(2)(C)), by inserting "or section 564A".~~

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018".

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

Sec. 1. Short title; table of contents.

Sec. 2. References in Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.
Sec. 202. Amendments to preparedness and response programs.
Sec. 203. Regional health care emergency preparedness and response systems.
Sec. 204. Military and civilian partnership for trauma readiness.
Sec. 205. Public health and health care system situational awareness and biosurveillance capabilities.
Sec. 206. Strengthening and supporting the public health emergency rapid response fund.
Sec. 207. Improving preparedness for and response to all-hazards by public health emergency volunteers.
Sec. 208. Clarifying State liability law for volunteer health care professionals.

TITLE III—REACHING ALL COMMUNITIES

Sec. 301. Strengthening and assessing the emergency response workforce.
Sec. 302. Health system infrastructure to improve preparedness and response.
Sec. 303. Considerations for at-risk individuals.
Sec. 304. Improving emergency preparedness and response considerations for children.
Sec. 305. Reauthorizing the National Advisory Committee on Children and Disasters.
Sec. 306. Authorizing the National Advisory Committee on Seniors and Disasters.
Sec. 307. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

Sec. 401. Assistant Secretary for Preparedness and Response.
Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
Sec. 403. Strategic National Stockpile.
Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.
Sec. 405. Reporting on the Federal Select Agent Program.

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

Sec. 501. Medical countermeasure budget plan.
Sec. 502. Material threat and medical countermeasure notifications.
Sec. 503. Availability of regulatory management plans.
Sec. 504. The Biomedical Advanced Research and Development Authority and the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

Sec. 601. Administration of countermeasures.
Sec. 602. Medical countermeasure master files.
Sec. 603. Priority zoonotic animal drugs.
Sec. 604. Animal rule report.

Sec. 605. Review of the benefits of genomic engineering technologies and their potential role in national security.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. Reauthorizations and extensions.
Sec. 702. Technical amendments.

SEC. 2. REFERENCES IN ACT.

Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "2014" and inserting "2018"; and

(ii) by striking the second sentence and inserting the following: "Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with

the national preparedness goal (as described in section 504(a)(19) of the Homeland Security Act of 2002), the National Incident Management System (as defined in section 501(7) of such Act), and the National Response Plan developed pursuant to section 504 of such Act, or any successor plan.";

(B) in paragraph (2), by inserting before the period at the end of the second sentence the following: ", and an analysis of any changes to the evidence-based benchmarks and objective standards under sections 319C–1 and 319C–2"; and

(C) in paragraph (3)—

(i) by striking "2009" and inserting "2022";

(ii) by inserting "(including gaps in the environmental health and animal health workforces, as applicable), describing the status of such workforce" after "gaps in such workforce";

(iii) by striking "and identifying strategies" and inserting "identifying strategies"; and

(iv) by inserting before the period at the end ", and identifying current capabilities to meet the requirements of section 2803"; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking "and investigation" and inserting "investigation, and related information technology activities";

(ii) in subparagraph (B), by striking "and decontamination" and inserting "decontamination, relevant health care services and supplies, and transportation and disposal of medical waste"; and

(iii) by adding at the end the following:

"(E) Response to environmental hazards.";

(B) in paragraph (3)(F), by inserting "or exposures to agents that could cause a public health emergency" before the period;

(C) in paragraph (5), by inserting "and other applicable compacts" after "Compact"; and

(D) by adding at the end the following:

"(9) ZOONOTIC DISEASE, FOOD, AND AGRICULTURE.—Improving coordination among Federal, State, local, tribal, and territorial entities (including through consultation with the Secretary of Agriculture) to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease) that could compromise national security resulting from a deliberate attack, a naturally occurring threat, the intentional adulteration of food, or other public health threats, taking into account interactions between animal health, human health, and animals' and humans' shared environment as directly related to public health emergency preparedness and response capabilities, as applicable.

"(10) GLOBAL HEALTH SECURITY.—Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.".

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR PREPAREDNESS AND RESPONSE.

(a) EVALUATING MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—Section

319C–1 (42 U.S.C. 247d–3a) is amended by inserting after subsection (j) the following:

"(k) EVALUATION.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

"(2) CONTENT.—The evaluation under this paragraph shall include—

"(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

"(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of

the National Health Security Strategy under section 2802;

"(C) a description of amounts received by eligible entities, as described in subsection (b) and section 319C–2(b), and amounts received by subrecipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

"(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accurately assess the ability of entities receiving awards under this section to better achieve the goals under this section and section 2802.".

(b) EVALUATING THE PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–2(i)(1) (42 U.S.C. 247–3b(i)(1)) is amended by striking "section 319C–1(g), (i), and (j)" and inserting "section 319C–1(g), (i), (j), and (k)".

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS.

(a) COOPERATIVE AGREEMENT APPLICATIONS FOR IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Section 319C–1 (42 U.S.C. 247d–3a) is amended—

(1) in subsection (a), by inserting ", acting through the Director of the Centers for Disease Control and Prevention," after "the Secretary"; and

(2) in subsection (b)(2)(A)—

(A) in clause (vi), by inserting ", including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies," after "stakeholders";

(B) by redesignating clauses (vii) through (ix) as clauses (viii) through (x); and

(C) by inserting after clause (vi) the following:

"(vii) a description of how, as applicable, such entity may integrate information to account for individuals with behavioral health needs following a public health emergency;".

(b) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Section 319C–2 (42 U.S.C. 247d–3b) is amended—

(1) in subsection (a)—

(A) by inserting ", acting through the Assistant Secretary for Preparedness and Response," after "The Secretary"; and

(B) by striking "preparedness for public health emergencies" and inserting "preparedness for, and response to, public health emergencies in accordance with subsection (c)"; and

(2) in subsection (b)(1)(A)—

(A) in clause (iii), by redesignating subclauses (I) through (III) as items (aa) through (cc), respectively, and adjusting the margins accordingly;

(B) by redesignating clauses (i) through (iii) as subclauses (I) through (III) respectively, and adjusting the margins accordingly;

(C) by striking "partnership consisting of—" and inserting "partnership—

"(i) consisting of—"; and

(D) by adding at the end the following:

"(ii) that may include one or more emergency medical service organizations or emergency management organizations; and".

(c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking "$641,900,000 for fiscal year 2014" and all that follows through the period at the end and inserting "$685,000,000

for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)).".

(d) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is amended—

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

"(1) IN GENERAL.—

"(A) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 319C–3, in accordance with subparagraph (B), there is authorized to be appropriated $385,000,000 for each of fiscal years 2019 through 2023.

"(B) RESERVATIONS OF AMOUNTS FOR REGIONAL SYSTEMS.—

"(i) IN GENERAL.—Subject to clause (ii), of the amount appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve up to 5 percent for the purpose of carrying out section 319C–3.

"(ii) RESERVATIONS CONTINGENT ON CONTINUED APPROPRIATIONS FOR THIS SECTION.—If for fiscal year 2019 or a subsequent fiscal year, the amount appropriated under subparagraph (A) is such that, after application of clause (i), the amount remaining for the purpose of carrying out this section would be less than the amount available for such purpose for the previous fiscal year, the amount that may be reserved under clause (i) shall be reduced such that the amount remaining for the purpose of carrying out this section is not less than the amount available for such purpose for the previous fiscal year.

"(iii) SUNSET.—The authority to reserve amounts under clause (i) shall expire on September 30, 2023.";

(2) in paragraph (2), by striking "paragraph (1) for a fiscal year" and inserting "paragraph (1)(A) for a fiscal year and not reserved for the purpose described in paragraph (1)(B)(i)"; and

(3) in paragraph (3)(A), by striking "paragraph (1) and not reserved under paragraph (2)" and in-

serting "paragraph (1)(A) and not reserved under paragraph (1)(B)(i) or (2)".

SEC. 203. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

(a) IN GENERAL.—Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 319C–2 the following:

"SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

"(a) PURPOSE.—It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, in advance of, and immediately following a public health emergency, including threats posed by one or more chemical, biological, radiological, and nuclear agents, including emerging infectious diseases.

"(b) GUIDELINES.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, the Commissioner of Food and Drugs, the

Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Affairs, the heads of such other Federal agencies as the Secretary determines to be appropriate, and State, local, tribal, and territorial public health officials, shall, not later than 2 years after the date of enactment of this section—

"(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

"(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

"(i) the manner in which the system will coordinate with and integrate the part-

nerships and health care coalitions established under section 319C–2(b); and

"(ii) informing and educating appropriate first responders and health care supply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

"(B) physical and technological infrastructure, laboratory capacity, staffing, blood supply, and other supply chain needs, taking into account resiliency, geographic considerations, and rural considerations;

"(C) protocols or best practices for the safety and personal protection of workers who handle human remains and health care workers (including with respect to protective equipment and supplies, waste management processes, and decontamination), sharing of specialized experience among the health care workforce, behavioral health, psychological resilience, and training of the workforce, as applicable;

"(D) in a manner that allows for disease containment (within the meaning of section

2802(b)(2)(B)), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

"(E) the needs of children and other at-risk individuals;

"(2) make such guidelines available on the internet website of the Department of Health and Human Services in a manner that does not compromise national security; and

"(3) update such guidelines as appropriate, including based on input received pursuant to subsections (c), (e), and (f), to address new and emerging public health threats.

"(c) CONSIDERATIONS.—In identifying, developing, and updating guidelines under subsection (b), the Assistant Secretary for Preparedness and Response shall—

"(1) include input from hospitals and health care facilities (including health care coalitions under section 319C–2), State, local, tribal, and territorial public health departments, and health care or subject matter experts (including experts with relevant exper-

tise in chemical, biological, radiological, or nuclear threats, and emerging infectious disease), as the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

"(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care facilities (including hospitals, primary care clinics, community health centers, mental health facilities, ambulatory care facilities, and dental health facilities), pharmacies, emergency medical providers, trauma care providers, environmental health agencies, public health laboratories, poison control centers, blood banks, and other experts that the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

"(3) consider feedback related to financial implications for hospitals, health care facilities, public health agencies, laboratories, and other entities engaged in regional preparedness planning to implement and follow such guidelines, as applicable; and

"(4) consider financial requirements and potential incentives for entities to prepare for, and respond to, public health emergencies as part of the regional

health care emergency preparedness and response system.

"(d) TECHNICAL ASSISTANCE.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assistance and consultation towards meeting the guidelines described in subsection (b).

"(e) DEMONSTRATION PROJECT FOR REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE SYSTEMS.—

"(1) IN GENERAL.—The Assistant Secretary for Preparedness and Response may establish a demonstration project pursuant to the development and implementation of guidelines under subsection (b) to award grants to improve medical surge capacity for all hazards, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, tribal, territorial, and regional jurisdictions.

"(2) SUNSET.—The authority under this subsection shall expire on September 30, 2023.

"(f) GAO REPORT TO CONGRESS.—

"(1) REPORT.—Not later than 3 years after the date of enactment of this section, the Comptroller General of the United States (referred to in this subsection as the 'Comptroller General') shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, a report on the extent to which hospitals and health care facilities have implemented the recommended guidelines under subsection (b), including an analysis and evaluation of any challenges hospitals or health care facilities experienced in implementing such guidelines.

"(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

"(A) data on the preparedness and response capabilities that have been informed by the guidelines under subsection (b) to improve regional emergency health care preparedness and response capability, including hospital and health care facility capacity and medical surge capabilities to prepare for, and respond to, public health emergencies; and

"(B) recommendations to reduce gaps in incentives for regional health partners, including hospitals and health care facilities, to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a), which may include consideration of facilities participating in programs under section 319C–2, programs under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

"(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Comptroller General shall consult with the heads of appropriate Federal agencies, including—

"(A) the Assistant Secretary for Preparedness and Response;

"(B) the Director of the Centers for Disease Control and Prevention;

"(C) the Administrator of the Centers for Medicare & Medicaid Services;

"(D) the Assistant Secretary for Mental Health and Substance Use;

"(E) the Assistant Secretary of Labor for Occupational Safety and Health;

"(F) the Secretary of Veterans Affairs; and

"(G) the heads of such other Federal agencies as the Secretary determines appropriate.".

(b) ANNUAL REPORTS.—Section 319C–2(i)(1) (42 U.S.C. 247d–3b(i)(1)) is amended by inserting after the first sentence the following "The reports submitted under this paragraph shall also include progress towards the implementation of section 319C–3.".

(c) NATIONAL HEALTH SECURITY STRATEGY INCORPORATION OF REGIONALIZED EMERGENCY PREPAREDNESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended—

(1) in the matter preceding subparagraph (A), by striking "including mental health" and inserting "including pharmacies, mental health facilities,"; and

(2) by amending subparagraph (G) to read as follows:

"(G) Optimizing a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems, which may include the implementation

of guidelines for regional health care emergency preparedness and response systems under section 319C–3.".

(d) IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—

(1) STATE AND LOCAL SECURITY.—Section 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by striking ", and local emergency plans." and inserting ", local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.".

(2) PARTNERSHIPS.—Section 319C–2(d)(1)(A) (42 U.S.C. 247d-3b(d)(1)(A)) is amended—

(A) in clause (i), by striking "; and" and inserting ";"

(B) by redesignating clause (ii) as clause (iii); and

(C) inserting after clause (i), the following:

"(ii) among one or more facilities in a regional health care emergency system under section 319C–3; and".

SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS.

Title XII (42 U.S.C. 300d et seq.) is amended by adding at the end the following new part:

"PART I—MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM

"SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM.

"(a) MILITARY TRAUMA TEAM PLACEMENT PROGRAM.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Secretary of Defense, shall award grants to not more than 20 eligible high acuity trauma centers to enable military trauma teams to provide, on a full-time basis, trauma care and related acute care at such trauma centers.

"(2) LIMITATIONS.—In the case of a grant awarded under paragraph (1) to an eligible high acuity trauma center, such grant—

"(A) shall be for a period of not fewer than 3 fiscal years and not more than 5 fiscal years (and may be renewed at the end of such period); and

"(B) shall be in an amount that does not exceed $1,000,000 per fiscal year.

"(b) MILITARY TRAUMA CARE PROVIDER PLACEMENT PROGRAM.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Secretary of Defense, shall award grants to eligible trauma centers to enable military trauma care providers to provide trauma care and related acute care at such trauma centers.

"(2) LIMITATIONS.—In the case of a grant awarded under paragraph (1) to an eligible trauma center, such grant—

"(A) shall be for a period of at least 1 fiscal year and not more than 3 fiscal years (and may be renewed at the end of such period); and

"(B) shall be in an amount that does not exceed, in a fiscal year—

"(i) $100,000 for each military trauma care provider that is a physician at such eligible trauma center; and

"(ii) $50,000 for each other military trauma care provider at such eligible trauma center.

"(c) GRANT REQUIREMENTS.—

"(1) DEPLOYMENT AND PUBLIC HEALTH EMERGENCIES.—As a condition of receipt of a grant under this section, a grant recipient shall agree to allow military trauma care providers providing care pursuant to such grant to—

"(A) be deployed by the Secretary of Defense for military operations, for training, or for response to a mass casualty incident; and

"(B) be deployed by the Secretary of Health and Human Services for response to a public health emergency pursuant to section 319.

"(2) USE OF FUNDS.—Grants awarded under this section to an eligible trauma center may be used to train and incorporate military trauma care providers into such trauma center, including incorporation into operational exercises and training drills related to public health emergencies, expenditures for malpractice insurance, office space, information technology, specialty education and supervision, trauma programs, and State license fees for such military trauma care providers.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect any other provision of law that preempts State licensing requirements for health care

professionals with respect to military trauma care providers.

"(e) REPORTING REQUIREMENTS.—

"(1) REPORT TO THE SECRETARY AND THE SECRETARY OF DEFENSE.—Each eligible trauma center or eligible high acuity trauma center awarded a grant under subsection (a) or (b) for a fiscal year shall submit to the Secretary and the Secretary of Defense a report for such fiscal year that includes information on—

"(A) the number and types of trauma cases managed by military trauma teams or military trauma care providers pursuant to such grant during such fiscal year;

"(B) the ability to maintain the integration of the military trauma providers or teams of providers as part of the trauma center, including the financial effect of such grant on the trauma center;

"(C) the educational effect on resident trainees in centers where military trauma teams are assigned;

"(D) any research conducted during such fiscal year supported by such grant; and

"(E) any other information required by the Secretaries for the purpose of evaluating the effect of such grant.

"(2) REPORT TO CONGRESS.—Not less than once every 2 fiscal years, the Secretary, in consultation with the Secretary of Defense, shall submit a report to the congressional committees of jurisdiction that includes information on the effect of placing military trauma care providers in trauma centers awarded grants under this section on—

"(A) maintaining military trauma care providers' readiness and ability to respond to and treat battlefield injuries;

"(B) providing health care to civilian trauma patients in urban and rural settings;

"(C) the capability of trauma centers and military trauma care providers to increase medical surge capacity, including as a result of a large scale event;

"(D) the ability of grant recipients to maintain the integration of the military trauma providers or teams of providers as part of the trauma center;

"(E) efforts to incorporate military trauma care providers into operational exercises and

training and drills for public health emergencies; and

"(F) the capability of military trauma care providers to participate as part of a medical response during or in advance of a declared public health emergency.

"(f) DEFINITIONS.—For purposes of this part:

"(1) ELIGIBLE TRAUMA CENTER.—The term 'eligible trauma center' means a Level I, II, or III trauma center that satisfies each of the following:

"(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma care providers to provide trauma care and related acute care at such trauma center.

"(B) Such trauma center utilizes a risk-adjusted benchmarking system and metrics to measure performance, quality, and patient outcomes.

"(C) Such trauma center demonstrates a need for integrated military trauma care providers to maintain or improve the trauma clinical capability of such trauma center.

"(2) ELIGIBLE HIGH ACUITY TRAUMA CENTER.—The term 'eligible high acuity trauma center' means

a Level I trauma center that satisfies each of the following:

"(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma teams to provide trauma care and related acute care at such trauma center.

"(B) At least 20 percent of patients treated at such trauma center in the most recent 3-month period for which data is available are treated for a major trauma at such trauma center.

"(C) Such trauma center utilizes a risk-adjusted benchmarking system and metrics to measure performance, quality, and patient outcomes.

"(D) Such trauma center is an academic training center—

"(i) affiliated with a medical school;

"(ii) that maintains residency programs and fellowships in critical trauma specialties and subspecialties, and provides education and supervision of military trauma team members according to those specialties and subspecialties; and

"(iii) that undertakes research in the prevention and treatment of traumatic injury.

"(E) Such trauma center serves as a medical and public health preparedness and response leader for its community, such as by participating in a partnership for State and regional hospital preparedness established under section 319C–2 or 319C–3.

"(3) MAJOR TRAUMA.—The term 'major trauma' means an injury that is greater than or equal to 15 on the injury severity score.

"(4) MILITARY TRAUMA TEAM.—The term 'military trauma team' means a complete military trauma team consisting of military trauma care providers specializing in providing trauma care.

"(5) MILITARY TRAUMA CARE PROVIDER.—The term 'military trauma care provider' means a member of the Armed Forces who furnishes emergency, critical care, and other trauma acute care services, including a physician, surgeon or military surgeon, physician assistant, nurse, nurse practitioner, respiratory therapist, flight paramedic, combat medic, or enlisted medical technician, or other military trau-

ma care provider as the Secretary determines appropriate.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $6,800,000 for each of fiscal years 2019 through 2023.".

SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SITUATIONAL AWARENESS AND BIOSURVEILLANCE CAPABILITIES.

(a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE CAPABILITIES.—Section 319D (42 U.S.C. 247d–4) is amended—

*(1) in the section heading, by striking "**REVITALIZING**" and inserting "**FACILITIES AND CAPACITIES OF**";*

(2) in subsection (a)—

(A) in the subsection heading, by striking "FACILITIES; CAPACITIES" and inserting "IN GENERAL";

(B) in paragraph (1), by striking "and improved" and inserting ", improved, and appropriately maintained";

(C) in paragraph (3), in the matter preceding subparagraph (A), by striking "expand, enhance, and improve" and inserting "expand,

improve, enhance, and appropriately maintain";
and

(D) by adding at the end the following:

"(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years 2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.";

(3) in subsection (b)—

(A) in the subsection heading, by striking "NATIONAL" and inserting "ESTABLISHMENT OF SYSTEMS OF PUBLIC HEALTH ";

(B) in paragraph (1)(B), by inserting "immunization information systems," after "centers,"; and

(C) in paragraph (2)—

(i) by inserting "develop a plan to, and" after "The Secretary shall"; and

(ii) by inserting "and in a form readily usable for analytical approaches" after "in a secure manner"; and

(D) by amending paragraph (3) to read as follows:

"(3) STANDARDS.—

"(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in cooperation with health care providers, State, local, tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under para-

graph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

"(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.";

(4) in subsection (c)—

(A) in paragraph (1)—

(i) by striking "Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary" and inserting "The Secretary";

(ii) by inserting ", and improve as applicable and appropriate," after "shall establish";

(iii) by striking "of rapid" and inserting "of, rapid"; and

(iv) by striking "such connectivity" and inserting "such interoperability";

(B) by amending paragraph (2) to read as follows:

"(2) COORDINATION AND CONSULTATION.—In establishing and improving the network under paragraph (1) the Secretary shall—

"(A) facilitate coordination among agencies within the Department of Health and Human Services that provide, or have the potential to provide, information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

"(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, and the Secretary of Veterans Affairs, and the heads of other Fed-

eral agencies, as the Secretary determines appropriate.";

(C) in paragraph (3)—

(i) by redesignating subparagraphs (A) through (E) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (iv), as so redesignated—

(I) by inserting "immunization information systems," after "poison control,"; and

(II) by striking " and clinical laboratories" and inserting ", clinical laboratories, and public environmental health agencies";

(iii) by striking "The network" and inserting the following:

"(A) IN GENERAL.—The network"; and

(iv) by adding at the end the following:

"(B) REVIEW.—Not later than 2 years after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such re-

view shall include a discussion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.";

(D) in paragraph (5)—

(i) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively, and adjusting the margins accordingly;

(ii) by striking "In establishing" and inserting the following:

"(A) IN GENERAL.—In establishing";

(iii) by adding at the end the following:

"(B) PUBLIC MEETING.—

"(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of

the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

"(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting); and other representatives as the Secretary determines appropriate.

"(iii) TOPICS.—Such public meeting shall include a discussion of—

"(I) data elements, including minimal or essential data elements, that are voluntarily provided for such network, which may include elements

from public health and public and private health care entities, to the extent practicable;

"(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

"(III) strategies to encourage the access, exchange, and use of information;

"(IV) considerations for State, local, tribal, and territorial capabilities and infrastructure related to data exchange and interoperability;

"(V) privacy and security protections provided at the Federal, State, local, tribal, and territorial levels, and by nongovernmental stakeholders; and

"(VI) opportunities for the incorporation of innovative technologies to improve the network."; and

(iv) in subparagraph (A), as so designated by clause (ii)—

(I) in clause (i), as so redesignated—

(aa) by striking "as determined" and inserting "as adopted"; and

(bb) by inserting "and the National Institute of Standards and Technology" after "Office of the National Coordinator for Health Information Technology";

(II) in clause (iii), as so redesignated, by striking "; and" and inserting a semicolon;

(III) in clause (iv), as so redesignated, by striking the period and inserting "; and"; and

(IV) by adding at the end the following:

"(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, tribal, and territorial public health entities may utilize, on a voluntary basis, as a part of the network.";

(E) by redesignating paragraph (6) as paragraph (7);

(F) by inserting after paragraph (5) the following:

"(6) STRATEGY AND IMPLEMENTATION PLAN.—

"(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan that—

"(i) is informed by the public meeting under paragraph (5)(B);

"(ii) includes a review and assessment of existing capabilities of the network and related infrastructure, including input provided by the public meeting under paragraph (5)(B);

"(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

"(I) develop, implement, and evaluate the network described in para-

graph (1), utilizing elements described in paragraph (3)(A);

"(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting for pandemics and all-hazards) from public and private entities;

"(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies; and

"(IV) test and evaluate capabilities of the interoperable network of systems to improve situational awareness and biosurveillance capabilities;

"(iv) includes performance measures and the metrics by which performance

measures will be assessed with respect to the measurable steps under clause (iii); and

"(v) establishes dates by which each measurable step under clause (iii) will be implemented.".

"(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

"(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

"(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strat-

egy and implementation plan under subparagraph (A);

"(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance capabilities, resources, and authorities needed to address such gaps; and

"(iv) a strategy to minimize and address such gaps and improve inefficiencies.";

(G) in paragraph (7), as so redesignated—

(i) in subparagraph (A), by inserting "(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)" after "human health";

(ii) in subparagraph (B)—

(I) by inserting "and gaps in surveillance programs" after "surveillance programs"; and

(II) by striking "; and" and inserting a semicolon;

(iii) in subparagraph (C)—

(I) by inserting ", animal health organizations related to zoonotic disease," after "health care entities"; and

(II) by striking the period and inserting "; and"; and

(iv) by adding at the end the following:

"(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 2802."; and

(H) by adding at the end the following:

"(8) SITUATIONAL AWARENESS AND BIOSURVEILLANCE AS A NATIONAL SECURITY PRIORITY.—The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development and capabilities of the nationwide public health situational awareness and biosurveillance network.";

(5) in subsection (d)—

(A) in paragraph (1)—

(i) by inserting "environmental health agencies," after "public health agencies,"; and

(ii) by inserting "immunization programs," after "poison control centers,"; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking "and" at the end;

(ii) in subparagraph (C), by striking the period and inserting "; and"; and

(iii) by adding after subparagraph (C) the following:

"(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1)."; and

(C) by striking paragraph (5) and inserting the following:

"(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, tribes, and territories or a consortium of States, localities, tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.";

(6) by redesignating subsections (f) and (g) as subsections (i) and (j), respectively; and

(7) by inserting after subsection (e) the following:

"(f) PERSONNEL AUTHORITIES.—

"(1) SPECIALLY QUALIFIED PERSONNEL.—In addition to any other personnel authorities, to carry out

subsection (b) and subsection (c), the Secretary may—

"(A) appoint highly qualified individuals to scientific or professional positions at the Centers for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

"(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in which individuals appointed under 9903 of title 5, United States Code, are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates.

"(2) LIMITATIONS.—The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 319F–1(e)(2).

"(g) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to the congressional committees of jurisdiction for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

"(h) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the congressional committees of jurisdiction a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.".

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (i) of section 319D (42 U.S.C. 247d–4), as redesignated by subsection (a)(6), is amended by striking "$138,300,000 for each of fiscal years 2014 through 2018" and inserting "$161,800,000 for each of fiscal years 2019 through 2023".

SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC HEALTH EMERGENCY RAPID RESPONSE FUND.

Section 319 (42 U.S.C. 247d) is amended—

(1) in subsection (b)—

(A) in paragraph (1)—

(i) in the first sentence, by inserting "or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency" before the period; and

(ii) by inserting "The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities." after the first sentence;

(B) by redesignating paragraph (2) as paragraph (3);

(C) by inserting after paragraph (1) the following:

"(2) USES.—The Secretary may use amounts in the Fund established under paragraph (1), to—

"(A) facilitate coordination between and among Federal, State, local, tribal, and terri-

torial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency (including communication of such entities with relevant international entities, as applicable);

"(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 319C–1, 319C–2, or 319C–3;

"(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

"(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such public health emergency or potential public health

emergency, including the systems under section 319D;

"(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel expenses under section 2812, and the Medical Reserve Corps under section 2813; and

"(F) other activities, as the Secretary determines applicable and appropriate."; and

(D) by inserting after paragraph (3), as so redesignated, the following:

"(4) REVIEW.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section, and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

"(5) GAO REPORT.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct a review of the Fund under this section, including the uses and the resources available in the Fund."; and

(2) in subsection (c)—

(A) by inserting "rapidly respond to public health emergencies or potential public health emergencies and" after "used to"; and

(B) by striking "section." and inserting "Act or funds otherwise provided for emergency response.".

SEC. 207. IMPROVING PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS BY PUBLIC HEALTH EMERGENCY VOLUNTEERS.

Section 319I (42 U.S.C. 247d–7b) is amended:

(1) in subsection (a), by adding at the end the following: "Such health care professionals may include members of the National Disaster Medical System, members of the Medical Reserve Corps, and individual health care professionals.";

(2) in subsection (i) by adding at the end "In order to inform the development of such mechanisms

by States, the Secretary shall make available information and material provided by States that have developed mechanisms to waive the application of licensing requirements to applicable health professionals seeking to provide medical services during a public health emergency. Such information shall be made publicly available in a manner that does not compromise national security.''; and

(3) in subsection (k) by striking ''2014 through 2018'' and inserting ''2019 through 2023''.

SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

(a) IN GENERAL.—Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 319I the following:

''SEC. 319I–1. HEALTH CARE PROFESSIONALS ASSISTING DURING A PUBLIC HEALTH EMERGENCY.

''(a) LIMITATION ON LIABILITY.—Notwithstanding any other provision of law, a health care professional who is a member of the Medical Reserve Corps under section 2813 or who is included in the verification network under section 319I and who—

''(1) is responding to a public health emergency declared under section 319(a) during the initial 90-day period of the public health emergency determina-

tion (excluding any period covered by a renewal of such determination);

"(2) is alleged to be liable for an act or omission—

"(A) during the 90-day period of the public health emergency described in paragraph (1) and related to the treatment of individuals in need of health care services due to such public health emergency;

"(B) in the State or States in which the public health emergency is declared;

"(C) in the health care professional's capacity as a member of the Medical Reserve Corps or a professional included in the verification network under section 319I; and

"(D) in the course of providing services that are within the scope of the license, registration, or certification of the professional, as defined by the State of licensure, registration, or certification; and

"(3) prior to the rendering of such act or omission, was authorized by the State's authorization of a deploying State's Emergency System for Advance Registration of Volunteer Health Professionals described in section 319I or the Medical Reserve Corps

established under section 2813, to provide health care services,

shall be subject only to the State liability laws of the State in which such act or omission occurred, in the same manner and to the same extent as a similar health care professional who is a resident of such State would be subject to such State laws, except with respect to the licensure, registration, and certification of such individual.

"(b) VOLUNTEER PROTECTION ACT.—Nothing in this section shall be construed to affect an individual's right to protections under the Volunteer Protection Act of 1997.

"(c) PREEMPTION.—This section shall supercede the laws of any State that would subject a health care professional described in subsection (a) to the liability laws of any State other than the State liability laws to which such individual is subject pursuant to such subsection.

"(d) DEFINITIONS.—In this section:

"(1) The term 'health care professional' means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.

"(2) The term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional, that relate to—

"(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

"(B) the assessment or care of the health of human beings.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Section 319I–1 of the Public Health Service Act, as added by subsection (a), shall take effect 90 days after the date of the enactment of this Act.

(2) APPLICATION.—Section 319I–1 of the Public Health Service Act, as added by subsection (a), applies to a claim for harm only if the act or omission that caused such harm occurred on or after the effective date described in paragraph (1).

(c) GAO STUDY.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a review of—

(1) the number of health care providers who register under the verification network pursuant to section 319I of the Public Health Service Act (42 U.S.C. 247d–7b) in advance to provide services during a public health emergency;

(2) the number of health care providers who are credentialed to provide services during the period of a public health emergency declaration, including

those who are credentialed though programs established in the verification network pursuant to such section 319I and those credentialed by authorities within the State in which the emergency occurred;

(3) the average time to verify the credentials of a health care provider during the period of a public health emergency declaration, including the average time pursuant to the verification network under such section 319I and for an individual's credentials to be verified by an authority within the State; and

(4) the States' Emergency System for Advance Registration of Volunteer Health Professionals volunteer program, including whether physician or medical groups, associations, or other relevant provider organizations utilize such program for purposes of volunteering during public health emergencies.

TITLE III—REACHING ALL COMMUNITIES

SEC. 301. STRENGTHENING AND ASSESSING THE EMERGENCY RESPONSE WORKFORCE.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause (ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh–11(a)(3)(A)) is amended to read as follows:

"(ii) be present at locations, and for limited periods of time, specified by the Sec-

retary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified, or there is a significant potential for a public health emergency.".

(b) VOLUNTEER MEDICAL RESERVE CORPS.—Section 2813(a) (42 U.S.C. 42 U.S.C. 300hh–15(a)) is amended by striking the second sentence and inserting "The Secretary may appoint a Director to head the Corps and oversee the activities of the Corps chapters that exist at the State, local, tribal, and territorial levels."

(c) REVIEW OF THE NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh–11(b)(2)) is amended to read as follows:

"(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—

"(A) REVIEW.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include—

"(i) an evaluation of medical surge capacity, as described in section 2803(a);

"(ii) an assessment of the available workforce of the intermittent disaster response personnel described in subsection (c);

"(iii) the capacity of the workforce described in clause (ii) to respond to all hazards, including capacity to simultaneously respond to multiple public health emergencies and the capacity to respond to a nationwide public health emergency;

"(iv) the effectiveness of efforts to recruit, retain, and train such workforce; and

"(v) gaps that may exist in such workforce and recommendations for addressing such gaps.

"(B) UPDATES.—As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from the review under subparagraph (A) and provide recommendations to modify the policies of the National Disaster Medical System as necessary.".

(d) NOTIFICATION OF NDMS SHORTAGE.—Section 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding at the end the following:

"(3) SERVICE BENEFIT.—Individuals appointed to serve under this subsection shall be considered public safety officers under part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968. The Secretary shall provide notification to eligible individuals of any effect such designation may have on other benefits for which such individuals are eligible, including benefits from private entities.

"(4) NOTIFICATION.—Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster response personnel of such System is insufficient to address a public health emergency or potential public health emergency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency, and any identified measures to address such shortage.

"(5) CERTAIN APPOINTMENTS.—

"(A) IN GENERAL.—If the Secretary determines that the number of intermittent disaster response personnel within the National Disaster Medical System under this section is insufficient to address a public health emergency or potential

public health emergency, the Secretary may appoint candidates directly to personnel positions for intermittent disaster response within such system. The Secretary shall provide updates on the number of vacant or unfilled positions within such system to the congressional committees of jurisdiction each quarter for which this authority is in effect.

"(B) SUNSET.—The authority under this paragraph shall expire on September 30, 2021.".

(e) PUBLIC SAFETY OFFICER BENEFITS.—Section 1204(9) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

(1) in subparagraph (C)(ii), by striking "or" at the end;

(2) in subparagraph (D), by striking the period and inserting "; or"; and

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

"(E) an individual appointed to the National Disaster Medical System under section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) who is performing official duties of the Department of Health and Human Services, if those official duties are related to responding

to a public health emergency or potential public health emergency, or other activities for which the Secretary of Health and Human Services has activated such National Disaster Medical System.".

(f) NATIONAL DISASTER MEDICAL SYSTEM AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) (42 U.S.C. 300hh–11(g)) is amended by striking "$52,700,000 for each of fiscal years 2014 through 2018" and inserting "$57,400,000 for each of fiscal years 2019 through 2023".

(g) MEDICAL RESERVE CORPS. AUTHORIZATION OF APPROPRIATIONS.—Section 2813(i) (42 U.S.C. 300hh–15(i)) is amended by striking "2014 through 2018" and inserting "2019 through 2023".

SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE PREPAREDNESS AND RESPONSE.

(a) COORDINATION OF PREPAREDNESS.—Section 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by adding at the end the following: "Such logistical support shall include working with other relevant Federal, State, local, tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including

entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including an emergency under section 319, an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.''.

(b) MANUFACTURING CAPACITY.—Section 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting '', and ancillary medical supplies to assist with the utilization of such products,'' after ''products''.

SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.

(a) AT-RISK INDIVIDUALS IN THE NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B) (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

(1) by striking ''this section and sections 319C–1, 319F, and 319L,'' and inserting ''this Act''; and

(2) by striking ''special'' and inserting ''access or functional''.

(b) COUNTERMEASURE CONSIDERATIONS.—Section 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

(1) by striking ''elderly'' and inserting ''senior citizens''; and

(2) by inserting "with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products" before the period.

SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND RESPONSE CONSIDERATIONS FOR CHILDREN.

Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 319D the following:

"SEC. 319D–1. CHILDREN'S PREPAREDNESS UNIT.

"(a) ENHANCING EMERGENCY PREPAREDNESS FOR CHILDREN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this subsection as the 'Director'), shall maintain an internal team of experts, to be known as the Children's Preparedness Unit (referred to in this subsection as the 'Unit'), to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Unit shall inform the Director regarding emergency preparedness and response efforts pertaining to children at the Centers for Disease Control and Prevention.

"(b) EXPERTISE.—The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavioral pediatrician, and may also include behavioral scientists, child psychologists, epidemiolo-

gists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

"(c) DUTIES.—The team described in subsection (a) may—

"(1) assist State, local, tribal, and territorial emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

"(2) provide technical assistance, training, and consultation to Federal, State, local, tribal, and territorial public health officials to improve preparedness and response capabilities with respect to the needs of children, including providing such technical assistance, training, and consultation to eligible entities in order to support the achievement of measurable evidence-based benchmarks and objective standards applicable to sections 319C–1 and 319C–2 ;

"(3) improve the utilization of methods to incorporate the needs of children in planning for and responding to a public health emergency, including public awareness of such methods;

"(4) coordinate with, and improve, public-private partnerships, such as health care coalitions pursuant to sections 319C–2 and 319C–3, to address gaps

and inefficiencies in emergency preparedness and response efforts for children;

"(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies, including pursuant to section 319C–3; and

"(6) carry out other duties related to preparedness and response activities for children, as the Secretary determines appropriate.".

SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

Section 2811A (42 U.S.C. 300hh–10a) is amended—

(1) in subsection (b)(2), by inserting ", mental and behavioral," after "medical";

(2) in subsection (d)—

(A) in paragraph (1), by striking "15" and inserting "25"; and

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

"(2) REQUIRED NON-FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1)

at least 13 individuals to perform the duties described in subsections (b) and (c), including—

"(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

"(B) at least 2 representatives from State, local, tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

"(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents and emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

"(D) other members as the Secretary determines appropriate, of whom—

"(i) at least one such member shall represent a children's hospital;

"(ii) at least one such member shall be an individual with expertise in schools or child care settings;

"(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

"(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities.".

"(3) FEDERAL MEMBERS.—The Advisory Committee under paragraph (1) shall include the following Federal members or their designees:

"(A) The Assistant Secretary for Preparedness and Response.

"(B) The Director of the Biomedical Advanced Research and Development Authority.

"(C) The Director of the Centers for Disease Control and Prevention.

"(D) The Commissioner of Food and Drugs.

"(E) The Director of the National Institutes of Health.

"(F) The Assistant Secretary of the Administration for Children and Families.

"(G) The Administrator of the Health Resources and Services Administration.

"(H) The Administrator of the Federal Emergency Management Agency.

"(I) The Administrator of the Administration for Community Living.

"(J) The Secretary of Education.

"(K) Representatives from such Federal agencies (such as the Substance Abuse and Mental Health Services Administration and the Department of Homeland Security) as the Secretary determines appropriate to fulfill the duties of the Advisory Committee under subsections (b) and (c).".

"(4) TERM OF APPOINTMENT.—Each member of the Advisory Committee appointed under paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the Advisory Committee appointees serving on the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, or appointees who are initially appointed after such date of enactment,

in order to provide for a staggered term of appointment for all members.

"(5) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member appointed under paragraph (2) may serve not more than 3 terms on the Advisory Committee, and not more than 2 of which may be served consecutively.";

(3) in subsection (e), by adding at the end "At least one meeting per year shall be an in-person meeting.";

(4) by redesignating subsection (f) as subsection (g);

(5) by inserting after subsection (e) the following:

"(f) COORDINATION.—The Secretary shall coordinate activities authorized under this section and section 2811B, in accordance with section 2811B(d)."; and

(6) in subsection (g), as so redesignated, by striking "2018" and inserting "2023".

SEC. 306. AUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

Subtitle B of title XXVIII (42 U.S.C. 300hh et seq.) is amended by inserting after section 2811A the following:

"SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

"(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Veterans Affairs, shall establish an advisory committee to be known as the National Advisory Committee on Seniors and Disasters (referred to in this section as the 'Advisory Committee').

"(b) DUTIES.—

"(1) IN GENERAL.—The Advisory Committee shall—

"(A) provide advice and consultation with respect to the activities carried out pursuant to section 2814, as applicable and appropriate;

"(B) evaluate and provide input with respect to the medical and public health needs of seniors related to the preparation for, response to, and recovery from all-hazards emergencies; and

"(C) provide advice and consultation with respect to State emergency preparedness and response activities and seniors, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

"(2) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to

the Secretary with respect to seniors and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this title and title III.

"(3) MEMBERSHIP.—

"(A) IN GENERAL.—The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

"(B) REQUIRED MEMBERS.—The members appointed under paragraph (1) shall include—

"(i) the Assistant Secretary for Preparedness and Response;

"(ii) the Director of the Biomedical Advanced Research and Development Authority;

"(iii) the Director of the Centers for Disease Control and Prevention;

"(iv) the Commissioner of Food and Drugs;

"(v) the Director of the National Institutes of Health;

"(vi) the Administrator of the Centers for Medicare & Medicaid Services;

"(vii) the Administrator of the Administration for Community Living;

"(viii) the Administrator of the Federal Emergency Management Agency;

"(ix) the Under Secretary for Health of the Department of Veterans Affairs;

"(x) at least 2 non-Federal health care professionals with expertise in medical disaster planning, preparedness, response, or recovery;

"(xi) at least 2 representatives of State, local, territorial, or tribal agencies with expertise in disaster planning, preparedness, response, or recovery; and

"(xii) representatives of such other Federal agencies (such as the Department of Energy and the Department of Homeland Security) as the Secretary determines necessary to fulfill the duties of the Advisory Committee.

"(c) MEETINGS.—The Advisory Committee shall meet not less frequently than biannually.

"(d) ADVISORY COMMITTEE COORDINATION.—

"(1) IN GENERAL.—The Secretary shall coordinate activities authorized under this section and section 2811A, and make efforts to reduce unnecessary or duplication of meetings, recommendations, and reporting under such sections. Members of the advisory committees under this section and section 2811A, or their designees, shall meet periodically, and not less than annually, to—

"(A) review the recommendations developed by such committees to coordinate, as appropriate, the implementation of recommendations, in order to reduce gaps, overlap, and duplication of effort in Federal programs or by Federal grantees; and

"(B) align preparedness and response programs or activities to address the dual or overlapping needs of children and seniors and any challenges in preparing for and responding to such needs.

"(2) NOTIFICATION.—The Secretary shall notify the congressional committees of jurisdiction upon the convening of each meeting under paragraph (1), and provide minutes from such meeting not later than 90 days after the meeting.

"(e) SUNSET.—The Advisory Committee shall terminate on September 30, 2023.".

SEC. 307. GUIDANCE FOR PARTICIPATION IN EXERCISES AND DRILLS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance regarding the participation of State, local, tribal, and territorial public health department or agency personnel funded in whole or in part through programs authorized under this Act in drills and operational exercises in order to identify, inform, and address the gaps in and policies related to all-hazards medical and public health preparedness and response, which may include drills and operational exercises that incorporate medical surge capacity planning, medical countermeasure distribution and administration, and preparing for and responding to identified threats for that region. The Secretary shall consult with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies as necessary and appropriate in the development of such guidance. The Secretary shall make the guidance available on the internet website of the Department of Health and Human Services.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811(b) (42 U.S.C. 300hh–10(b)) is amended—

(1) in the matter preceding paragraph (1) by inserting "utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to" after "shall"; and

(2) in paragraph (4) by adding at the end the following:

"(I) THREAT AWARENESS.—Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, and other relevant Federal officials, such as the Secretary of Agriculture, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.".

SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

(a) IN GENERAL.—Title XXVIII is amended by inserting after section 2811 (42 U.S.C. 300hh–10) the following:

"SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

"(a) IN GENERAL.—The Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the 'PHEMCE'). The Assistant Secretary for Preparedness and Response shall serve as chair of the PHEMCE.

"(b) MEMBERS.—The PHEMCE shall include each of the following members, or the designee of such members:

"(1) The Assistant Secretary for Preparedness and Response.

"(2) The Director of the Centers for Disease Control and Prevention.

"(3) The Director of the National Institutes of Health.

"(4) The Commissioner of Food and Drugs.

"(5) The Secretary of Defense.

"(6) The Secretary of Homeland Security.

"(7) The Secretary of Agriculture.

"(8) The Secretary of Veterans Affairs.

"(9) Representatives of any other Federal agency, which may include the Director of the Biomedical

Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the Secretary determines appropriate.

"(c) FUNCTIONS.—

"(1) IN GENERAL.—The functions of the PHEMCE shall include the following:

"(A) Establish a process pursuant to section 2811(d)(2)(B) to make recommendations to the Secretary regarding the prioritization of research, development, and procurement of countermeasures, as defined in section 319F–2(c), based on the health security needs of the United States. Such recommendations shall be informed by the National Health Security Strategy pursuant to section 2802, the Strategic National Stockpile review required under section 319F–2(a)(2), the countermeasures budget plan pursuant to section 2811(b)(7), and an assessment of current national security threats, including chemical, biological, radiological and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree

upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

"(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures and challenges to addressing such needs (including any regulatory challenges), and provide for alignment of countermeasure procurement with recommendations under subparagraph (A).

"(C) Develop strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 319F–2(a).

"(D) Provide consultation for the development of the strategy and implementation plan under section 2811(d).

"(2) INPUT.—In carrying out subparagraphs (B) and (C) of paragraph (1), the PHEMCE shall solicit and consider input from State, local, tribal, and territorial public health departments, as appropriate.".

(b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION

PLAN.—Section 2811(d) (42 U.S.C. 300hh–10(d)) is amended—

(1) in paragraph (1)—

(A) by striking "Not later than 180 days after the date of enactment of this subsection, and every year thereafter" and inserting "Not later than March 15, 2020, and biennially thereafter"; and

(B) by striking "Director of Biomedical" and all that follows through "Food and Drugs" and inserting "Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1"; and

(2) in paragraph (2)(J)(v), by striking "one-year period" and inserting "2-year period".

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

(a) Section 319F–2(a) (42 U.S.C. 247d–6b(a)) is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) in paragraph (1)—

(A) by inserting "and optimize" after "provide for";

(B) by inserting "and, as informed by existing recommendations of, or consultations with,

the Public Health Emergency Medical Countermeasure Enterprise established under section 2811–1, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2)" before the period of the first sentence; and

(C) by striking the second sentence;

(3) by inserting after paragraph (1) the following:

"(2) THREAT-BASED REVIEW.—

"(A) IN GENERAL.—The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review shall be submitted annually, beginning on March 15, 2019, to the Committee on Health, Education, Labor, and Pensions and the Committee on Ap-

propriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, in a manner that does not compromise national security.

"(B) ADDITIONS, MODIFICATIONS, AND REPLENISHMENTS.—Each annual threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

"(i) information regarding—

"(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

"(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;

"(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

"(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

"(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emergency preparedness to address such threats;

"(VI) whether such countermeasure is replenishing an expired countermeasure, is a different countermeasure with the same indication that is replacing an expired countermeasure, or is a new addition to the stockpile;

"(VII) a description of how such additions or modifications align with the countermeasures budget plan as required under section 2811(b)(7), including expected life-cycle costs, expenditures related to countermeasure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

"(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabilities of State and local entities to dispense, distribute, and administer the countermeasure; and

"(ii) an assurance that for each countermeasure produced or replenished under this subsection, the Secretary completed a review addressing each item listed under

this subsection in advance of such procurement or replenishment, which need not be provided in advance of procurement.";

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

(A) in subparagraph (A), by inserting "and the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1" before the semicolon;

(B) in subparagraph (C), by inserting ", and the availability, deployment, dispensing, and administration of countermeasures" before the semicolon; and

(C) by amending subparagraph (E) to read as follows:

"(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies, State, local, tribal, and territorial agencies, and the public and private health care infrastructure, as applicable, taking into account

the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;" and

(5) by adding at the end the following:

"(5) GAO REPORT.—

"(A) IN GENERAL.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

"(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

"(ii) an assessment of whether the Secretary established health security and

science-based justifications, and a description of such justifications for procurement decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

"(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

"(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

"(v) an analysis of how such procurement decisions made progress towards meet-

ing emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

"(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the emergency health security needs of the stockpile;

"(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General; and

"(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled

countermeasures, and use of resources for such activities.

"(B) SUBMISSION.—Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an unclassified version of the review to the congressional committees of jurisdiction.".

(b) AUTHORIZATION OF APPROPRIATIONS, STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42 U.S.C. 247d–6b(f)(1)) is amended by striking "$533,800,000 for each of fiscal years 2014 through 2018" and inserting "$610,000,000 for each of fiscal years 2019 through 2023".

SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTIMICROBIAL RESISTANCE, AND OTHER SIGNIFICANT THREATS.

Section 319L(c)(4) (247d–7e(c)(4)) is amended by adding at the end the following:

"(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding grants supporting innovative candidate products in preclinical and clinical development, to address priority, naturally occurring and

man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, countermeasures and products, as applicable, to address areas including—

"(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

"(ii) threats that consistently exist or continually circulate and have significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manu-

facturing, 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); and

"(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.".

SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT PROGRAM.

Section 351A(k) (42 U.S.C. 262a) is amended—

(1) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary"; and

(2) by adding at the end the following:

"(2) IMPLEMENTATION OF RECOMMENDATIONS OF THE FEDERAL EXPERTS SECURITY ADVISORY PANEL AND THE FAST TRACK ACTION COMMITTEE ON SELECT AGENT REGULATIONS.—

"(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

"(B) CONTINUED UPDATES.—The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.".

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking "March 1" and inserting "March 15";

(2) by striking subparagraph (A) and inserting the following:

"(A) include consideration of the entire medical countermeasures enterprise, including—

"(i) basic research and advanced research and development;

"(ii) approval, clearance, licensure, and authorized uses of products;

"(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile; and

"(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and

opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development;".

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

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

"(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;".

SEC. 502. MATERIAL THREAT AND MEDICAL COUNTERMEASURE NOTIFICATIONS.

(a) CONGRESSIONAL NOTIFICATION OF MATERIAL THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42 U.S.C. 247d-6b(c)(2)(C)) is amended by striking "The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress" and inserting "The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pen-

sions and the Committee on Homeland Security and Government Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives".

(b) CONTRACTING COMMUNICATIONS.—

(1) CONTRACT DURATION.—Section 319F–2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–6b(c)(7)(B)(ii)(III)) is amended by adding at the end the following: "The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew such contract.".

(2) EXPEDITED AUTHORITIES.—Section 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is amended by adding at the end the following: "Upon award, extension, or termination of any such contract, grant, cooperative agreement, and other transaction, the Secretary shall provide a written notification to the receiving entity that includes a justification for such award, extension, or termination.".

SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT PLANS.

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

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

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

"(3) PUBLICATION.—The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

"(A) the process by which an applicant may submit a request for a regulatory management plan;

"(B) the timeframe by which the Secretary is required to respond to such request;

"(C) the information required for the submission of such request;

"(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

"(E) contact information for beginning the regulatory management plan process.";

(3) in paragraph (6), as so redesignated, in the matter preceding subparagraph (A)—

(A) by striking "paragraph (4)(A)" and inserting "paragraph (5)(A)"; and

(B) by striking "paragraph (4)(B)" and inserting "paragraph (5)(B)"; and

(4) in paragraph (7)(A), as so redesignated, by striking "paragraph (3)(A)" and inserting "paragraph (4)(A)".

SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY AND THE BIOSHIELD SPECIAL RESERVE FUND.

(a) BIOSHIELD SPECIAL RESERVE FUND.—Section 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

(1) by striking "$2,800,000,000 for the period of fiscal years 2014 through 2018" and inserting "$3,500,000,000 for the period of fiscal years 2019 through 2023, to remain available until expended"; and

(2) by striking the second sentence.

(b) THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42 U.S.C. 247d–7e(d)(2)) is amended by striking "$415,000,000 for each of fiscal years 2014 through 2018" and inserting "$611,700,000 for each of fiscal years 2019 through 2023".

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

SEC. 601. ADMINISTRATION OF COUNTERMEASURES.

Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–7e(c)(4)(D)(iii)) is amended by striking "and platform

technologies'' inserting ''platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures''.

SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 565A the following:

''SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

''(a) PURPOSE.—The purpose of this section is to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encouraging submission of data and information to support such products to master files, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary.

''(b) APPLICABILITY OF REFERENCE.—

''(1) IN GENERAL.—A person may submit data and information to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized

to reference the master file. Such data and information shall be available for reference by the master file holder or a person authorized by the master file holder only in accordance with applicable privacy and confidentiality protocols and regulations.

"(2) MASTER FILE HOLDER.—In this section, the term 'master file holder' means a person who submits data and information to the Secretary with the intent to reference or authorize to reference such data or information to support a medical countermeasure submission, as described in paragraph (1).

"(c) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

"(1) IN GENERAL.—A master file under this section may include information to support and accelerate—

"(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

"(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

"(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

"(d) SPONSOR REFERENCE.—

"(1) IN GENERAL.—Each incorporation of information or data contained in a master file by reference shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such information without necessitating resubmission of such information or data. Master files shall be submitted in an electronic format in accordance with section 745A and as specified in applicable guidance.

"(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

"(3) REFERENCE BY AN AUTHORIZED PERSON.—A sponsor of a medical countermeasure submission may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a

medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

"(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE SECRETARY.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified information or data within a master file and the purposes for which such information or data was incorporated by reference if the Secretary has reviewed and relied upon such specified information or data to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

"(f) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the authority of the Secretary to approve, license, classify, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to this Act or section 351 of the Public

Health Service Act (as authorized prior to the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act; or

"(2) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of information or data previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 505(i), 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

"(g) DEFINITIONS.—In this section:

"(1) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of

the Public Health Service Act or a biosimilar biological product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or request for an emergency use authorization under section 564 to support—

"(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

"(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

"(2) The terms 'qualified countermeasure', 'security countermeasure', and 'qualified pandemic or epidemic product' have the meanings given such terms in

sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act.".

(b) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through the reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) GUIDANCE.—Not later than 2 years after the after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish

draft guidance about how reliance on cross-referenced data and information contained within master files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

SEC. 603. PRIORITY ZOONOTIC ANIMAL DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 512 the following:

"SEC. 512A. PRIORITY ZOONOTIC ANIMAL DRUGS.

"(a) DESIGNATION OF A NEW ANIMAL DRUG AS A PRIORITY ZOONOTIC ANIMAL DRUG.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of an application for approval of a new animal drug under section 512(b)(1) or an application for conditional approval of a new animal drug under section 571, expedite the development and review of such new animal drug if preliminary clin-

ical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

"(2) REQUEST FOR DESIGNATION.—The sponsor of a new animal drug may request the Secretary to designate a new animal drug described in paragraph (1) as a priority zoonotic animal drug. A request for the designation may be made concurrently with, or at any time after, the opening of an investigational new animal drug file under section 512(j) or the filing of an application under section 512(b)(1) or 571.

"(3) DESIGNATION.—

"(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the new animal drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary determines that the new animal drug meets the criteria, the Secretary shall designate the new animal drug as a priority zoonotic animal drug and shall take

such actions as are appropriate to expedite the development and review of the application for approval or conditional approval of such new animal drug.

"(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

"(i) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies;

"(ii) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

"(iii) involving senior managers and review staff with experience in zoonotic or

vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and

"(iv) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.".

SEC. 604. ANIMAL RULE REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the application of the requirements under section 565(d) of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d)) (referred to in this section as the "animal rule") as a component of medical countermeasure advanced development under the Biomedical Advanced Research and Development Authority and regulatory review by the Food and Drug Administration. In conducting such study, the Comptroller General shall examine the following:

(1) The extent to which advanced development and review of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug Administration, including activities facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal

rule, consistent with the recommendations in the animal rule guidance, issued pursuant to section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled "Product Development Under the Animal Rule Guidance for Industry" (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.

(2) The consistency of the application of the animal rule among and between review divisions within the Food and Drug Administration.

(3) The flexibilities pursuant to the animal rule to address variations in countermeasure development and review processes, including the extent to which qualified animal models are adopted and used within the Food and Drug Administration in regulatory decisionmaking with respect to medical countermeasures.

(4) The extent to which the guidance issued under section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled, "Product Development Under the Animal Rule Guid-

ance for Industry" (issued in October 2015), has assisted in achieving the purposes described in paragraphs (1), (2), and (3).

(b) CONSULTATIONS.—In conducting the study under subsection (a), the Comptroller General of the United States shall consult with—

(1) the Federal agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Department of Defense;

(2) manufacturers involved in the research and development of medical countermeasures to address biological, chemical, radiological, and nuclear threats; and

(3) other biodefense stakeholders, as applicable.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a) and recommendations to improve the appli-

cation and consistency of the requirements under subsections (c) and (d) of section 565 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this section in a manner that does not compromise national security.

SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGINEERING TECHNOLOGIES AND THEIR POTENTIAL ROLE IN NATIONAL SECURITY.

(a) MEETING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall convene a meeting to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security. Such meeting shall be held in a manner that does not compromise national security.

(2) ATTENDEES.—The attendees of the meeting under paragraph (1)—

(A) shall include—

(i) representatives from the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration; and

(ii) representatives from academic, private, and non-profit entities with expertise in genome engineering technologies, biopharmaceuticals, medicine, or biodefense, and other relevant stakeholders; and

(B) may include—

(i) other representatives from the Department of Health and Human Services, as the Secretary determines appropriate; and

(ii) representatives from the Department of Homeland Security, the Department of Defense, the Department of Agriculture, and other departments, as the Secretary may request for the meeting.

(3) TOPICS.—The meeting under paragraph (1) shall include a discussion of—

(A) the current state of the science of genomic engineering technologies related to national health security, including—

(i) medical countermeasure development, including potential efficiencies in the development pathway and detection technologies; and

(ii) the international and domestic regulation of products utilizing genome editing technologies; and

(B) national security implications, including—

(i) capabilities of the United States to leverage genomic engineering technologies as a part of the medical countermeasure enterprise, including current applicable research, development, and application efforts underway within the Department of Defense;

(ii) the potential for state and non-state actors to utilize genomic engineering technologies as a national health security threat; and

(iii) security measures to monitor and assess the potential threat of genomic engi-

neering technologies and related technologies.

(b) REPORT.—Not later than 180 days after the meeting described in subsection (a) is held, the Assistant Secretary for Preparedness and Response shall issue a report to the congressional committees of jurisdiction on the topics discussed at such meeting, and provide recommendations, as applicable, to utilize innovations in genomic engineering (including genome editing) and related technologies as a part of preparedness and response activities to advance national health security. Such report shall be issued in a manner that does not compromise national security.

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

(a) VETERANS AFFAIRS.—Section 8117(g) of title 38, United States Code, is amended by striking "2014 through 2018" and inserting "2019 through 2023".

(b) VACCINE TRACKING AND DISTRIBUTION.—Section 319A(e) (42 U.S.C. 247d–1(e)) is amended by striking "2014 through 2018" and inserting "2019 through 2023".

(c) TEMPORARY REASSIGNMENT.—Section 319(e)(8) (42 U.S.C. 247d(e)(8)) is amended by striking "2018" and inserting "2023".

(d) STRATEGIC INNOVATION PARTNER.—Section 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking "2022" and inserting "2023".

(e) PUBLIC DISCLOSURE EXEMPTION.—Section 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking "12" and inserting "17".

(f) LIMITED ANTITRUST EXEMPTION.—

(1) IN GENERAL.—Section 405 of the Pandemic and All-Hazards Preparedness Act (42 U.S.C. 247d–6a note) is amended—

(A) by redesignating such section as section 319L–1;

(B) transferring such section to the Public Health Service Act (42 U.S.C. 201 et seq.), to appear after section 319L of such Act (42 U.S.C. 247d–7e);

(C) in subsection (a)(1)—

(i) by striking "Secretary of Health and Human Services (referred to in this subsection as the 'Secretary')" and inserting "Secretary";

(ii) by striking "of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act";

(iii) by striking "of the Public Health Service Act (42 U.S.C. 247d– 6a)) (as amended by this Act"; and

(iv) by striking "of the Public Health Service Act (42 U.S.C. 247d–6d)"; and

(D) in subsection (b), by striking "12-year" and inserting "17-year".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1)(D) shall take effect as if enacted on December 17, 2012.

(3) CONFORMING AMENDMENT.—The table of contents in section 1(b) of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) is amended by striking the item related to section 405.

SEC. 702. TECHNICAL AMENDMENTS.

(a) PUBLIC HEALTH SERVICE ACT.—Title III (42 U.S.C. 241 et seq.) is amended—

(1) in paragraphs (1) and (5) of section 319F–1(a) (42 U.S.C. 247d–6a(a)), by striking "section 319F(h)" each place such term appears and inserting "section 319F(e)"; and

(2) in section 319K(a) (42 U.S.C. 247d–7d(a)), by striking "section 319F(h)(4)" and inserting "section 319F(e)(4)".

(b) PUBLIC HEALTH SECURITY GRANTS.—Section 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

(1) in subparagraph (C), by striking "individuals,," and inserting "individuals,"; and

(2) in subparagraph (F), by striking "make satisfactory annual improvement and describe" and inserting "makes satisfactory annual improvement and describes".

(c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 564A(e)(2)(A) (21 U.S.C. 360bbb–3a(e)(2)(A)), by striking "subsection (a)(1)(C)(i)" and inserting "subsection (a)(1)(C)"; and

(2) in section 564B(2)(C) (21 U.S.C. 360bbb–3b(2)(C)), by inserting "or section 564A".

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115TH CONGRESS
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S. 2852

A BILL

To reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.

JUNE 18, 2018

Reported with an amendment