115TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____

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

A BILL

To reauthorize certain programs under the 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.

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 public health emergency preparedness and response systems.
Sec. 204. Public health situational awareness and biosurveillance capabilities.
Sec. 205. Strengthening and supporting the public health emergency [bridge] 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. BARDA 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.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 of the Public Health Service Act (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 public health threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to respond to such threats and shall be consistent with the National Preparedness Goal, the National Incident Management System, and the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, 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’’;

(C) in paragraph (3)—

(i) by striking ‘‘2009’’ and inserting ‘‘2018’’;

(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 capabilities to meet the requirements of section 2803’’;

(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 ‘‘de-

contamination, health care services and necessary medical 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'' after ''workplace exposures'';

(C) by amending 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, and tribal entities to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease) resulting from a deliberate attack, the intentional adulteration of food, or other public health threats that could compromise national security, taking into account interactions between animal health, human health, and environmental health 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 of the Public Health Service Act (42 U.S.C. 247d–3a(g)) 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 performance measures and evidence-based benchmarks and objective standards that assess the ability of awardees to accomplish the activities described in this section and section 319C–2. Such evaluation shall be submitted to the relevant committees of Congress together with the National Health Security Strategy

under section 2802, at such time as such strategy is submitted.

''(2) CONTENTS.—The evaluation under this paragraph shall include—

''(A) a review of performance measures and associated metrics, targets, and evidence-based benchmarks;

''(B) a discussion of changes to any performance measures and evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether awardees 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 allocations with respect to amounts received by eligible entities under subsection (b) and section 319C–2(b) and amounts received by sub-recipients and the effect of such allocations on meeting performance measures and evidence-based benchmarks and objective standards; and

''(D) recommendations, as applicable and appropriate, to improve performance measures

and 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) of the Public Health Service Act (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 of the Public Health Service Act (42 U.S.C. 247d–3a(b)(2)(A)) 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) PUBLIC HEALTH SECURITY GRANTS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) of the Public Health Service Act (42 U.S.C. 247d–3a(h)(1)(A)) is amended—

(1) by striking ''$641,900,000 for fiscal year 2014'' and inserting ''**[**$xx**]** for fiscal year 2019''; and

(2) by striking ''$641,900,000 for each of fiscal years 2015 through 2018'' and inserting ''**[**$xx**]** for each of fiscal years 2020 through 2023''.

(c) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY AUTHORIZATION OF APPROPRIATIONS.—Section 319C–2(j)(1) of the Public Health Service Act (42 U.S.C. 247d–

3b(j)(1)) is amended by striking ''$374,700,000 for each of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** for each of fiscal years 2019 through 2023''.

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

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

''SEC. 319C–3. GUIDELINES FOR REGIONAL PUBLIC HEALTH 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 public health facilities 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 Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Affairs, such

other Federal agencies as the Secretary determines to be appropriate, and State, local, tribal, and territorial public health officials, shall, not later than 1 year of 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 applicable health care facilities and hospitals to provide appropriate patient care during or in advance of a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases, (which may include, as applicable and appropriate, existing practices such as trauma care and medical surge capacity and capabilities) with respect to—

''(A) establishing the capabilities of entities described in clauses (i) and (ii) of section 319C–2(b)(1)(A) to identify, evaluate, and provide exposure response and disease containment (within the meaning of section 2802(b)(2)(B));

''(B) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, which may include informing and educating appropriate

first responders to a public health emergency of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

''(C) physical infrastructure, laboratory capacity, and staffing needs, taking into account resiliency and geographic considerations;

''(D) protocols or best practices for health care worker safety and personal protection, including protective equipment and supplies, waste management processes and decontamination, and training, as applicable;

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

''(F) the needs of 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 to address new and emerging public health threats.

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

''(1) 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, State and local public health departments, environmental health agencies, public health laboratories, blood banks, and other health care experts, including experts with relevant expertise in chemical, biological, radiological, and nuclear threats, and emerging infectious diseases that the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3)(A);

''(2) consider feedback related to financial implications for health care facilities and hospitals to implement such guidelines, as applicable; and

''(3) consider financial requirements and potential incentives for facilities to prepare for and respond to public health emergencies.

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

''(e) GAO REPORT TO CONGRESS.—

''(1) REPORT.—Not later than 2 years after the date of enactment of this section, 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 health care facilities and hospitals have implemented the recommended guidelines under subsection (b), including an analysis and evaluation of any challenges health care facilities or hospitals experienced in implementing such guidelines.

''(2) IMPLEMENTATION OF GUIDELINES.—The Comptroller General shall include in the report under paragraph (1), data on the preparedness and

response capabilities that have been informed by the guidelines under subsection (b) to improve health care facilities and hospital capacity and medical surge capabilities to prepare for, and respond to, public health emergencies.

''(3) RECOMMENDATIONS.—Not later than 3 years after the date of enactment of this section, the Comptroller General shall submit to the Committees referred to in paragraph (1), recommendations to reduce gaps in incentives for health care facilities and hospitals to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a). Such recommendations may take into account facilities participating in programs under section 319C–2, programs under the jurisdiction of the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

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

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

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

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

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

"(E) the Secretary of Veterans Affairs; and

"(F) the heads of such other Federal agencies as the Secretary determines to be appropriate.".

(b) ANNUAL REPORTS.—Section 319C–2(i)(1) of the Public Health Service Act (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) of the Public Health Service Act (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,"; 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 public health 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) of the Public Health Service Act (42 U.S.C. 247d–3a(e)) is amended by striking '', and local emergency plans.'' and inserting '', local emergency plans, and any regional public health emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.''.

(2) PARTNERSHIPS.—Section 319C–2(d)(1)(A) of the Public Health Service Act (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 public health emergency system under section 319C–3; and''.]

[(e) TRAUMA SYSTEM IMPROVEMENTS.—TBS.]

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

(a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE CAPABILITIES.—Section 319D of the Public Health Service Act (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), 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.—The Comptroller General of the United States shall conduct a study on Federal spending for activities authorized under this subsection in fiscal years 2013 through 2018. Such study shall include a review and assessment of expenses directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, expenses incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the expenses incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and identify the agency or agencies incurring such expenses.'';

(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 ''(in a form readily usable for analytical approaches)'' after ''another public health emergency''; and

(D) by striking paragraph (3) and inserting the following:

''(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 and local 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 of this Act, 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 preference 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 ''enhanced systems that enable such connectivity'' and inserting ''enhanced systems that enable 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 (including 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 Pan-

demic 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 appropriate committees of Congress.'';

(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).

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

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

(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), 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 2 years after the date of enactment of the Pandemic 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, 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 (2)(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 such measures will be assessed with respect to the steps under subclause (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 section, 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 situa-

tional 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 capabilities, and resources [and/or 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 outlined in this subsection 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 [appropriate members of the intelligence community] in order to inform the development and capabilities of the na-

tionwide 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 goals under paragraph (1).''; and

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

''(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States or a consortium of States receiving an award under this sub-

section 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 goals and targets under this section no later than September 30, 2023, and shall provide a justification to Congress for any missed goals or targets.

''(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 this section, 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 of the Public Health Service Act (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 ''[$xx] for each of fiscal years 2019 through 2023''.

SEC. 205. STRENGTHENING AND SUPPORTING THE PUBLIC HEALTH EMERGENCY [BRIDGE] FUND.

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

(1) in subsection (b)—

(A) in the first sentence of paragraph (1), by inserting ''or if the Secretary determines there is the significant potential for a public health emergency [, to allow the Secretary to immediately respond to such public health emergency or potential public health emergency]'' before the period;

(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 (a), to—

''(A) facilitate coordination between and among Federal, State, local, tribal, and territorial entities that the Secretary determines may be affected by a public health emergency,

including further supporting programs under section 319C–1 or 319C–2;

''(B) 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);

''(C) 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;

''(D) 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

''(E) 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 such fund.''; and

(2) in subsection (c), by striking ''section.'' and inserting ''Act.''.

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

Section 319I of the Public Health Service Act (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 for 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 which does not jeopardize national security.''; and

(3) in subsection (k) by striking ''$5,000,000 for each of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** for each of fiscal years 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) of the Public Health Service Act (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) REVIEW OF THE NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812(b)(2) of the Public Health Service Act (42 U.S.C. 300hh–11(b)(2)) is amended to read as follows:

> ''(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—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 an evaluation of medical surge capacity, as described in section 2803(a), an assessment of the available workforce of the intermittent disaster response personnel, as described in subsection (c), and an assessment of the Medical Reserve Corps, as described in section 2813. Such workforce assessment shall include the capacity of such workforce to meet the needs of an all-hazards approach, including capacity to simultaneously respond to multiple public health emergencies and the potential capacity to respond to a nationwide public health emergency, the effectiveness of efforts to recruit, retain, and train the workforce, the gaps that may exist in the workforce, and recommendations for addressing such gaps. As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from such review and provide recommendations to modify the policies of the National Disaster Medical System and the Medical Reserve Corps as necessary.''.

(c) NOTIFICATION OF NDMS SHORTAGE.—Section 2812(c) of the Public Health Service Act (42 U.S.C.

300hh–11(c)) is amended by adding at the end the following:

''(3) 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 an on-going or potential public health emergency, the Secretary shall submit to the appropriate committees of Congress a notification detailing the impact such shortage could have on meeting public health and emergency medical personnel needs during a public health emergency, and any identified measures to address such issue.''.

(d) NATIONAL DISASTER MEDICAL SYSTEM AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) of the Public Health Service Act (42 U.S.C. 300hh–11(g)) is amended by striking ''$52,700,000 for each of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** for each of fiscal years 2019 through 2023''.

(e) MEDICAL RESERVE CORPS. AUTHORIZATION OF APPROPRIATIONS.—Section 2813(i) of the Public Health Service Act (42 U.S.C. 300hh–15(i)) is amended by striking ''$11,200,000 for each of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** for each of fiscal years 2019 through 2023''.

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

(a) COORDINATION OF PREPAREDNESS.—Section 2811(b)(5) of the Public Health Service Act (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 entities capable of assisting with, responding to, or mitigating the effect of a public health emergency under section 319, 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 goods].''.

(b) MANUFACTURING CAPACITY.—Section 2811(d)(2)(C) of the Public Health Service Act is amended by inserting '', and necessary medical supplies to assist with the utilization of such products,'' after ''products''.

(c) STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(a)(2)(E) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(2)(E)) is amended by inserting before the semicolon '', taking into account the manufacturing capacity and other available sources of products and supplies in the stockpile''.

SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.

(a) AT-RISK INDIVIDUALS IN THE NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B) of the Public Health Service Act (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) 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.

[[Section ____**]** of the Public Health Service Act is amended by inserting **[**xxx**]** the following:**]**

''**[**(____)**]** ENHANCING EMERGENCY PREPAREDNESS FOR CHILDREN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease

Control and Prevention, shall maintain an internal team of experts to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Director may rely upon the expertise of such team as part of emergency preparedness and response efforts at the Centers for Disease Control and Prevention.

''(2) EXPERTISE.—The team described in paragraph (1) shall be comprised of one or more pediatricians, including 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.

''(3) DUTIES.—The team described in paragraph (1) may—

''(A) assist State and local emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

''(B) provide technical assistance, training, and consultation to Federal, State, territorial, tribal, and local public health officials to im-

prove 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 under section 319C–1;

''(C) 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;

''(D) coordinate with, and improve, public-private partnerships to address gaps and inefficiencies in emergency preparedness and response efforts for children;

''(E) 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

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

(1) 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, may appoint to the Advisory Committee under paragraph (1) such individuals as may be appropriate to perform the duties described in subsections (b) and (c), which may include—

''(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, territorial, or tribal 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 who have experienced traumatic events; 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 Secretary, in consultation with such other heads of Federal agen-

cies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) 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; and

"(J) representatives from such Federal agencies (such as the Department of Education 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.'';

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

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

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

To be supplied.]

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811(b) of the Public Health Service Act (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, [domestic disaster preparedness,] 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 Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, [members of the intelligence community] and other relevant Federal officials, to 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 of the Public Health Service Act 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').

''(b) MEMBERS.—The PHEMCE shall consist of 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 Bio-

medical Advanced Research and Development Authority, and the Director of the Strategic National Stockpile, as the Secretary determines appropriate.

''(c) FUNCTIONS.—

''(1) IN GENERAL.—The PHEMCE shall carry out the following functions:

''(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 multi-year 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.

''(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, and use of countermeasures that may be applicable to the [activities/responsibilities] 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 paragraph (1)(C), the PHEMCE shall consider input from State and local public health departments, as appropriate.''.

(b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—Subsection (d)(1) of section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended 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) of the Public Health Service Act (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, in consultation with the Public Health Emergency Medical Countermeasure Enterprise 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) ANNUAL 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 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 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, to the extent that disclosure of such information does not compromise national security.

''(B) ADDITIONS, MODIFICATIONS, AND REPLENISHMENTS.—Such annual threat-based review shall, for each new or modified countermeasure procurement or replenishment, provide 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;

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

''(iv) the public health 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 public health threat or threats described in clause (iv) could be addressed in a manner that [uses fewer of the available resources] to meet such needs, without compromising the level of preparedness;

''(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 countermeasure 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 clause (iv), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure;

''(viii) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including the capability of State and local entities to dispense, distribute, and administer the countermeasure; and

''(ix) 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.'';

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

(A) in subparagraph (A), by inserting ''and the Public Health Emergency Medical

Countermeasures Enterprise under section 2811–1'' before the semicolon;

(B) by amending paragraph (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 and local agencies, and the public and private health care infrastructure, as applicable;'' 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 2015. Such review shall include—

"(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including indicating 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 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 deploy-

ment, 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 an advanced research and development contract 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) of the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))

is amended by striking ''$533,800,000 for each of fiscal years 2014 through 2018'' and inserting ''[$xx] for each of fiscal years 2019 through 2023''.

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

Section 319L(c)(4) of the Public Health Service Act (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, to address priority threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of the chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such threats (including medical response capabilities). Such initiatives shall advance innovation in, and 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 no approved, licensed, or authorized countermeasure exists, 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 which consistently exist or continually circulate and have significant potential to become a pandemic, 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 development of such countermeasures (including multiuse platform technologies for diagnostics, [virus seeds, clinical trial lots], novel virus strains, and antigen and adjuvant material); and

''(iii) threats that may result from a chemical, biological, radiological, or nuclear agent, and which may present increased

complications in treating a countermeasure resistant disease or condition resulting primarily or secondarily from such threats or agents, such as through the development of novel countermeasures for drug resistant organisms.''.

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

Section 351A(k) of the Public Health Service Act (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 provide an update to the appropriate committees of Congress on the implementation of recommendations of the Federal Experts Secu-

rity 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) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) 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 capacity) of all products in the Strategic National Stockpile;

"(iv) current manufacturing capabilities and capacity; and

"(v) 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;".

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

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

"(D) identify medical countermeasure anticipated research and development needs, 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) of the Public Health Service Act (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, the material threat list and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Government Affairs Committee of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives''.

(b) CONTRACTING COMMUNICATIONS.—Section 319F–2(c)(7)(ii)(III) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(ii)(III)) is amended by adding at the end the following: ''Upon a determination by the Secretary to renew such contract, the Secretary shall notify the vendor of such determination in as timely a manner as practicable.''.

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 summary of the milestones and performance targets that may be discussed and achieved, pursuant to paragraph (6); 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. BARDA AND THE BIOSHIELD SPECIAL RESERVE FUND.

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

(1) by striking ''$2,800,000,000 for the period of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** for the period of fiscal years 2019 through 2023''; and

(2) by striking ''2019'' and inserting ''2024''.

(b) BARDA.—Section 319L(d)(2) of the Public Health Service Act (42 U.S.C. 247d–7e(d)(2)) is amended by striking ''$415,000,000 for each of fiscal years 2014 through 2018'' and inserting ''**[**$xx**]** 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) of the Public Health Service Act (42 U.S.C. 247d-7e(c)(4)(D)(iii)) is amended by inserting ''technologies to administer countermeasures,'' before ''efficacy increasing technologies''.

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, as defined in subsection (g) (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.

''(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 described in subsection (g) to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or quali-

fied pandemic or epidemic products; [and]/[or]

''(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 described in subsection (g).

''(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 described in subsection (g) 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 described in subsection (g) 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 [notice/letter] indicating that the Secretary has reviewed and relied upon [specified] information or data within a master file and the purposes for which it 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 [notification/letter] was provided in additional applications, as applicable and appropriate and upon the request of the master file holder

[so notified/in receipt of the letter] 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 section 351 (a) or (k) 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 subsection (a) or (k) or section 351 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 the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, or 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, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, with respect to how the Food and Drug Administration can help 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 or submissions otherwise submitted to the Secretary may be used for specific tools or 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) as a component of medical countermeasure development and review under the Biomedical Advanced Research and Development Authority and the Food and Drug Administration. In conducting such study, the Comptroller General shall examine the following:

(1) The extent to which review and development of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug Administration, including activities to ensure such coordination and resolve discrepancies in the design of clinical studies relying on 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 in 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.

(4) The extent to which the guidance as required by section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb-4) titled ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October, 2015) has assisted in achieving the purposes under 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 Government agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Department of Health and Human Services, 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 sections 565(c) and 565(d) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb-4(c) and (d)) 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 ''$155,300,000 for each of fiscal years 2014 through 2018'' and inserting ''[$xx] for each of fiscal years 2019 through 2023''.

(b) VACCINE TRACKING AND DISTRIBUTION.—Section 319A(e) of the Public Health Service Act (42 U.S.C. 247d–1(e)) is amended by striking ''$30,800,000 for each of fiscal years 2014 through 2018'' and inserting ''[$xx] for each of fiscal years 2019 through 2023''.

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

(d) PUBLIC DISCLOSURE EXEMPTION.—Section 319L(e)(1)(C) of the Public Health Service Act (42 U.S.C. 47d–7e(e)(1)(C)) is amended by striking ''17''.

(e) EXTENSION OF LIMITED ANTITRUST EXEMPTION.—

(1) IN GENERAL.—Section 405(b) of the Pandemic and All-Hazards Preparedness Act (42 U.S.C. 247d–6a note) is amended by striking ''6-year'' and inserting ''17-year''.

(2) EFFECTIVE DATE.—This subsection shall take effect as if enacted on December 17, 2012.

SEC. 702. TECHNICAL AMENDMENTS.

(a) PUBLIC HEALTH SERVICE ACT.—Title III of the Public Health Service Act (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) of the Public Health Service Act (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''; and

(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)'';

(2) in section 564B(2)(C) (21 U.S.C. 360bbb-3b(2)(C)), by inserting ''or section 564A''; and

[(3) FDA national security concern language concern--section 507.**]**