A motion to reconsider was laid on the table.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT OF 2018

Mrs. BROOKS of Indiana. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6378) to reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6378

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:

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 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)—

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

(ii) in subparagraph (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 of the Public Health Service Act (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 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) 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) 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);

(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;'';

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

(E) in clause (x), as so redesignated, by inserting ''and'' after the semicolon; and

(F) by adding at the end the following:

''(xi) a description of how the entity will partner with health care facilities, including hospitals and nursing homes and other long-term care facilities, to promote and improve public health preparedness and response; and

''(xii) a description of how, as appropriate and practicable, the entity will include critical infrastructure partners, such as utility companies within the entity's jurisdiction, in planning pursuant to this subparagraph to help ensure that critical infrastructure will remain functioning during, or return to function as soon as practicable after, a public health emergency.''.

(b) EXCEPTION RELATING TO APPLICATION OF CERTAIN REQUIREMENTS.—

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

(A) in paragraph (5)—

(i) by striking ''Beginning with fiscal year 2009'' and inserting ''Beginning with fiscal year 2019'';

(ii) by striking ''for the immediately preceding fiscal year'' and inserting ''for either of the two immediately preceding fiscal years''; and

(iii) by striking ''2008'' and inserting ''2018''; and

(B) by amending subparagraph (A) of paragraph (6) to read as follows:

''(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

''(i) For one (but not both) of the first two fiscal years immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for the respective fiscal year.

''(ii) For one (but not both) of the first two fiscal years immediately following the third consecutive fiscal year in which an entity experienced such a failure, in lieu of applying clause (i), an amount equal to 15 percent of the amount the entity was eligible to receive for the respective fiscal year.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to cooperative agreements awarded on or after the date of enactment of this Act.

(c) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Section 319C–2 of the Public Health Service Act (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)'';

(2) in subsection (b)(1)(A)—

(A) by striking ''partnership consisting of'' and inserting ''coalition that includes'';

(B) in clause (ii), by striking ''; and'' and inserting a semicolon; and

(C) by adding at the end the following:

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

(3) in subsection (d)—

(A) in paragraph (1)(B), by striking ''partnership'' each place it appears and inserting ''coalition''; and

(B) in paragraph (2)(C), by striking ''medical preparedness'' and inserting ''preparedness and response'';

(4) in subsection (f), by striking ''partnership'' and inserting ''coalition'';

(5) in subsection (g)(2)—

(A) by striking ''Partnerships'' and inserting ''Coalitions'';

(B) by striking ''partnerships'' and inserting ''coalitions''; and

(C) by inserting ''and response'' after ''preparedness''; and

(6) in subsection (i)(1)—

(A) by striking ''An entity'' and inserting ''A coalition''; and

(B) by striking ''such partnership'' and inserting ''such coalition''.

(d) 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 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)).''.

(e) PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–2(j) of the Public Health Service Act (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) RESERVATION 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) RESERVATION 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 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 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 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, or 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 partnerships 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) and (e) and information resulting from applicable reports required under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (including any amendments made by such Act), 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, including emerging infectious diseases), 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, tissue 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, blood banks, tissue banks, 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 toward 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.''.

(b) GAO REPORT TO CONGRESS.—

(1) REPORT.—Not later than 3 years after the date of enactment of this Act, 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 section 319C–3(b) of the Public Health Service Act (as added by subsection (a)), 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 section 319C–3(b) of the Public Health Service Act 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 of the Public Health Service Act (42 U.S.C. 247d–3b) or in 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; and

(F) the Secretary of Veterans Affairs.

(c) 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 ''In submitting reports under this paragraph an entity shall include information on the progress that the entity has made toward the implementation of section 319C–3 (or barriers to progress, if any).''.

(d) NATIONAL HEALTH SECURITY STRATEGY INCORPORATION OF REGIONALIZED EMERGENCY PREPAREDNESS AND RESPONSE.—Subparagraph (G) of section 2802(b)(3) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(3)) is amended 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.''.

(e) 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 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) 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 health care emergency system under section 319C–3; and''.

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

Title XII of the Public Health Service Act (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 at least 3 years and not more than 5 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 year.

''(3) AVAILABILITY OF FUNDS.—Notwithstanding section 1552 of title 31, United States Code, or any other provision of law, funds available to the Secretary for obligation for a grant under this subsection shall remain available for expenditure for 100 days after the last day of the performance period of such grant.

''(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 year and not more than 3 years (and may be renewed at the end of such period); and

''(B) shall be in an amount that does not exceed, in a 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 Defense, in consultation with 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, research, and applicable 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, including 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 year shall submit to the Secretary and the Secretary of Defense a report for such 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 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 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 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 public health emergency, as determined by the Secretary, or a mass casualty incident.

''(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 are 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.

''(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, physician assistant, nurse, nurse practitioner, respiratory therapist, flight paramedic, combat medic, or enlisted medical technician), or other military trauma care provider as the Secretary determines appropriate.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $15,000,000 for each of fiscal years 2019 through 2023, of which—

''(1) ⅔ of the amount made available each fiscal year shall be made available for grants under subsection (a); and

''(2) ⅓ of the amount made available each fiscal year shall be made available for grants under subsection (b).''.

SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM 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), 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 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, 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 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 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; 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 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 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 subsections (b) and (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 such 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 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 ''$161,800,000 for each of fiscal years 2019 through 2023''.

(c) BIOLOGICAL THREAT DETECTION REPORT.—The Secretary of Health and Human Services shall, in coordination with the Secretary of Defense and the Secretary of Homeland Security, not later than 180 days after the date of enactment of this Act, report to the Committee on Energy and Commerce, the Committee on Armed Services, and the Committee on Homeland Security of the House of Representatives and the Committee on Health, Education, Labor, and Pensions, the Committee on Armed Services, and the Committee on Homeland Security and Governmental Affairs of the Senate on the state of Federal biological threat detection efforts, including the following—

(1) an identification of technological, operational, and programmatic successes and failures of domestic detection programs supported by Federal departments and agencies for intentionally-introduced or accidentally-released biological threat agents and naturally occurring infectious diseases;

(2) a description of Federal efforts to facilitate the exchange of information related to the information described in paragraph (1) among Federal departments and agencies that utilize biological threat detection technology;

(3) a description of the capabilities of detection systems in use by Federal departments and agencies including the capability to—

(A) rapidly detect, identify, characterize, and confirm the presence of biological threat agents;

(B) recover live biological agents from collection devices;

(C) determine the geographical distribution of biological agents;

(D) determine the extent of environmental contamination and persistence of biological agents; and

(E) provide advanced molecular diagnostics to State, local, tribal, and territorial public health and other laboratories that support biological threat detection activities;

(4) a description of Federal interagency coordination related to biological threat detection;

(5) a description of efforts by Federal departments and agencies that utilize biological threat detection technology to collaborate with State, local, tribal, and territorial public health laboratories and other users of biological threat detection systems, including collaboration regarding the development of—

(A) biological threat detection requirements or standards;

(B) a standardized integration strategy;

(C) training requirements or guidelines;

(D) guidelines for a coordinated public health response, including preparedness capabilities, and, as applicable, for coordination with public health surveillance systems; and

(E) a coordinated environmental remediation plan, as applicable; and

(6) recommendations related to research, advanced research, development, and procurement for Federal departments and agencies to improve and enhance biological threat detection systems, including recommendations on the transfer of biological threat detection technology among Federal departments and agencies, as necessary and appropriate.

SEC. 206. 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 referred to in paragraph (1) (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 under section 2812, and the Medical Reserve Corps under section 2813; and

''(F) carry out 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—

''(A) conduct a review of the Fund under this section, including its uses and the resources available in the Fund; and

''(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.''; 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 ALL-HAZARDS PREPAREDNESS AND RESPONSE BY PUBLIC HEALTH EMERGENCY VOLUNTEERS.

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

(1) in the section heading, by striking ''**HEALTH PROFESSIONS VOLUNTEERS**'' and inserting ''**VOLUNTEER HEALTH PROFESSIONAL**'';

(2) 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.'';

(3) 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

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

(b) ALL-HAZARDS PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE PLAN.—Section 319C–1(b)(2)(A)(iv) of the Public Health Service Act (42 U.S.C. 247d–3a(b)(2)(A)(iv)) is amended to read as follows:

''(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact, or other mutual aid agreement, for medical and public health mutual aid, and, as appropriate, the activities such entity will implement pursuant to section 319I to improve enrollment and coordination of volunteer health care professionals seeking to provide medical services during a public health emergency, which may include—

''(I) providing a public method of communication for purposes of volunteer coordination (such as a phone number);

''(II) providing for optional registration to participate in volunteer services during processes related to State medical licensing, registration, or certification or renewal of such licensing, registration or certification; or

''(III) other mechanisms as the State determines appropriate;''.

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

(a) IN GENERAL.—Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 224 the following:

''SEC. 225. 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 Emergency System for Advance Registration of Volunteer Health Professionals under section 319I and who—

''(1) is responding—

''(A) to a public health emergency determined under section 319(a), during the initial period of not more than 90 days (as determined by the Secretary) of the public health emergency determination (excluding any period covered by a renewal of such determination); or

''(B) to a major disaster or an emergency as declared by the President under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) or under section 201 of the National Emergencies Act (50 U.S.C.1621) during the initial period of such declaration; and

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

''(A) during the initial period of a determination or declaration described in paragraph (1) and related to the treatment of individuals in need of health care services due to such public health emergency, major disaster, or emergency;

''(B) in the State or States for which such determination or declaration is made;

''(C) in the health care professional's capacity as a member of the Medical Reserve Corps or a professional included in the Emergency System for Advance Registration of Volunteer Health Professionals 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 deploying such 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.

''(e) EFFECTIVE DATE.—

''(1) IN GENERAL.—This section shall take effect 90 days after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

''(2) APPLICATION.—This section shall apply 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).''.

(b) 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 Emergency System for Advance Registration of Volunteer Health Professionals under 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 Emergency System for Advance Registration of Volunteer Health Professionals under 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 Emergency System for Advance Registration of Volunteer Health Professionals under such section 319I and for an individual's credentials to be verified by an authority within the State; and

(4) the Emergency System for Advance Registration of Volunteer Health Professionals program in States, including whether physician or medical groups, associations, or other relevant provider organizations utilize such program for purposes of volunteering during public health emergencies.

SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUPPLY.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, including—

(1) challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate);

(2) ensuring the adequacy of the blood supply in the case of public health emergencies;

(3) implementation of the transfusion transmission monitoring system; and

(4) other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply.

SEC. 210. REPORT ON THE PUBLIC HEALTH PREPAREDNESS AND RESPONSE CAPABILITIES AND CAPACITIES OF HOSPITALS, LONG-TERM CARE FACILITIES, AND OTHER HEALTH CARE FACILITIES.

(a) STUDY.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the

Secretary of Health and Human Services shall enter into an agreement with an appropriate entity to conduct a study regarding the public health preparedness and response capabilities and medical surge capacities of hospitals, long-term care facilities, and other health care facilities to prepare for, and respond to, public health emergencies, including natural disasters.

(2) CONSULTATION.—In conducting the study under paragraph (1), the entity shall consult with Federal, State, local, tribal, and territorial public health officials (as appropriate), and health care providers and facilities with experience in public health preparedness and response activities.

(3) EVALUATION.—The study under paragraph (1) shall include—

(A) an evaluation of the current benchmarks and objective standards, as applicable, related to programs that support hospitals, long-term care facilities, and other health care facilities, and their effect on improving public health preparedness and response capabilities and medical surge capacities, including the Hospital Preparedness Program, the Public Health Emergency Preparedness cooperative agreements, and the Regional Health Care Emergency Preparedness and Response Systems under section 319C–3 of the Public Health Service Act (as added by section 203);

(B) the identification of gaps in preparedness, including with respect to such benchmarks and objective standards, such as those identified during recent public health emergencies, for hospitals, long-term care facilities, and other health care facilities to address future potential public health threats;

(C) an evaluation of coordination efforts between the recipients of Federal funding for programs described in subparagraph (A) and entities with expertise in emergency power systems and other critical infrastructure partners during a public health emergency, to ensure a functioning critical infrastructure, to the greatest extent practicable, during a public health emergency;

(D) an evaluation of coordination efforts between the recipients of Federal funding for programs described in subparagraph (A) and environmental health agencies with expertise in emergency preparedness and response planning for hospitals, long-term care facilities and other health care facilities; and

(E) an evaluation of current public health preparedness and response capabilities and medical surge capacities related to at-risk individuals during public health emergencies, including an identification of gaps in such preparedness as they relate to such individuals.

(b) REPORT.—

(1) IN GENERAL.—The agreement under subsection (a) shall require the entity to submit to the Secretary of Health and Human Services and the congressional committees of jurisdiction, not later than 3 years after the date of enactment of this Act, a report on the results of the study conducted pursuant to this section.

(2) CONTENTS.—The report under paragraph (1) shall—

(A) describe the findings and conclusions of the evaluation conducted pursuant to subsection (a); and

(B) provide recommendations for improving public health preparedness and response capability and medical surge capacity for hospitals, long-term care facilities, and other health care facilities, including—

(i) improving the existing benchmarks and objective standards for the Federal grant programs described in subsection (a)(3)(A) or developing new benchmarks and standards for such programs; and

(ii) identifying best practices for improving public health preparedness and response programs and medical surge capacity at hospitals, long-term care facilities, and other health care facilities, including recommendations for the evaluation under subparagraphs (C) and (D) of subsection (a)(3).

TITLE III—REACHING ALL COMMUNITIES

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

(a) NATIONAL DISASTER MEDICAL SYSTEM.—

(1) STRENGTHENING THE 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.''.

(2) 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.—

''(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.''.

(3) NOTIFICATION OF 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 the National Disaster Medical 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—

''(A) the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency; and

''(B) any identified measures to address such shortage.

''(4) 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.''.

(4) 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 ''$57,400,000 for each of fiscal years 2019 through 2023''.

(b) VOLUNTEER MEDICAL RESERVE CORPS.—

(1) IN GENERAL.—Section 2813(a) of the Public Health Service Act (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.''.

(2) AUTHORIZATION OF APPROPRIATIONS.—Section 2813(i) of the Public Health Service Act (42 U.S.C. 300hh–15(i)) is amended by striking ''2014 through 2018'' and inserting ''2019 through 2023''.

(c) STRENGTHENING THE EPIDEMIC INTELLIGENCE SERVICE.—Section 317F of the Public Health Service Act (42 U.S.C. Sec. 247b–7) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by inserting ''or preparedness and response activities, including rapid response to public health emergencies and significant public health threats'' after ''conduct prevention activities''; and

(ii) by striking ''$35,000'' and inserting ''$50,000''; and

(B) in paragraph (2)(B), by striking ''3 years'' and inserting ''2 years''; and

(2) in subsection (c)—

(A) by striking ''For the purpose of carrying out this section'' and inserting the following:

''(1) IN GENERAL.—For the purpose of carrying out this section, except as described in paragraph (2)''; and

(B) by adding at the end the following:

''(2) EPIDEMIC INTELLIGENCE SERVICE PROGRAM.—For purposes of carrying out this section with respect to qualified health professionals serving in the Epidemic Intelligence Service, as authorized under section 317G, there are authorized to be appropriated $1,000,000 for each of fiscal years 2019 through 2023.''.

(d) SERVICE BENEFIT FOR NATIONAL DISASTER MEDICAL SYSTEM VOLUNTEERS.—

(1) IN GENERAL.—Section 2812(c) of the Public Health Service Act (42 U.S.C. 300hh–11(c)), as amended by subsection (a)(3), is further amended by adding at the end the following:

''(5) SERVICE BENEFIT.—Individuals appointed to serve under this subsection shall be considered eligible for benefits 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 individual are eligible, including benefits from private entities.''.

(2) 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—

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

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

(C) 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—

''(i) 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; and

''(ii) determined by the Secretary of Health and Human Services to be hazardous.''.

(3) SUNSET.—The amendments made by paragraphs (1) and (2) shall cease to have force or effect on October 1, 2021.

(e) MISSION READINESS REPORT TO CONGRESS.—

(1) REPORT.—Not later than one year 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 of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the medical surge capacity of the United States in the event of a public health emergency, including the capacity and capability of the current health care workforce to prepare for, and respond to the full range of public health emergencies or potential public health emergencies, and recommendations to address any gaps identified in such workforce.

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

(A) the number of health care providers who have volunteered to provide health care services during a public health emergency, including members of the National Disaster Medical System, the Disaster Medical Assistant Teams, the Medical Reserve Corps, and other volunteer health care professionals in the verification network pursuant to section 319I of the Public Health Service Act (42 U.S.C. 247d–7b);

(B) the capacity of the workforce described in subparagraph (A) to respond to a public health emergency or potential public health emergency, including the capacity to respond to multiple concurrent public health emergencies and the capacity to respond to a nationwide public health emergency;

(C) the preparedness and response capabilities and mission readiness of the workforce described in subparagraph (A) taking into account areas of health care expertise and considerations for at-risk individuals (as defined in section 2802(b)(4)(B) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(4)(B));

(D) an assessment of the effectiveness of efforts to recruit, retain, and train such workforce; and

(E) identification of gaps that may exist in such workforce and recommendations for addressing such gaps, the extent to which the Assistant Secretary for Preparedness and Response plans to address such gaps, and any recommendations from the Comptroller General to address such gaps.

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 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 a public health emergency determined by the Secretary pursuant to section 319(a), an emergency or major disaster declared by the President 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) of the Public Health Service Act (42 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting '', and ancillary medical supplies to assist with the utilization of such countermeasures or products,'' after ''products''.

(c) EVALUATION OF BARRIERS TO RAPID DELIVERY OF MEDICAL COUNTERMEASURES.—

(1) RAPID DELIVERY STUDY.—The Assistant Secretary for Preparedness and Response may conduct a study on issues that have the potential to adversely affect the handling and rapid delivery of medical countermeasures to individuals during public health emergencies occurring in the United States.

(2) NOTICE TO CONGRESS.—Not later than 9 months after the date of the enactment of this Act, the Assistant Secretary for Preparedness and Response shall notify the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate if the Assistant Secretary for Preparedness and Response does not plan to conduct the study under paragraph (1) and shall provide such committees a summary explanation for such decision.

(3) REPORT TO CONGRESS.—Not later than 1 year after the Assistant Secretary for Preparedness and Response conducts the study under paragraph (1), such Assistant Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate containing the findings of such study.

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) of the Public Health Service Act (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.

(c) BIOSURVEILLANCE OF EMERGING PUBLIC HEALTH THREATS.—Section 2814 is amended—

(1) in paragraph (7), by striking ''; and'' and inserting a semicolon;

(2) in paragraph (8), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(9) facilitate coordination to ensure that, in implementing the situational awareness and biosurveillance network under section 319D, the Secretary considers incorporating data and information from Federal, State, local, tribal, and territorial public health officials and entities relevant to detecting emerging public health threats that may affect at-risk individuals, such as pregnant and postpartum women and infants, including adverse health outcomes of such populations related to such emerging public health threats.''.

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

Part B of title III of the Public Health Service Act (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, 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, 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. NATIONAL ADVISORY COMMITTEES ON DISASTERS.

(a) 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 (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, 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, including 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 (who may be non-voting members, as determined by the Secretary):

''(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 such terms 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 duties and activities authorized under this section in accordance with section 2811D.''; and

(6) in subsection (g), as so redesignated, by striking ''2018'' and inserting ''2023''.

(b) AUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.—Subtitle B of title XXVIII of the Public Health Service Act (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.—The Advisory Committee shall—

''(1) provide advice and consultation with respect to the activities carried out pursuant to section 2814, as applicable and appropriate;

''(2) evaluate and provide input with respect to the medical and public health needs of seniors related to preparation for, response to, and recovery from all-hazards emergencies; and

''(3) provide advice and consultation with respect to State emergency preparedness and response activities relating to seniors, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

''(c) 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.

''(d) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 17 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.

''(2) REQUIRED MEMBERS.—The Advisory Committee shall include Federal members or their designees (who may be non-voting members, as determined by the Secretary) and non-Federal members, as follows:

''(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 Administrator of the Centers for Medicare & Medicaid Services.

''(G) The Administrator of the Administration for Community Living.

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

''(I) The Under Secretary for Health of the Department of Veterans Affairs.

''(J) At least 2 non-Federal health care professionals with expertise in geriatric medical disaster planning, preparedness, response, or recovery.

''(K) At least 2 representatives of State, local, territorial, or tribal agencies with expertise in geriatric disaster planning, preparedness, response, or recovery.

''(L) 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.

''(e) MEETINGS.—The Advisory Committee shall meet not less frequently than biannually. At least one meeting per year shall be an in-person meeting.

''(f) COORDINATION.—The Secretary shall coordinate duties and activities authorized under this section in accordance with section 2811D.

''(g) SUNSET.—

''(1) IN GENERAL.—The Advisory Committee shall terminate on September 30, 2023.

''(2) EXTENSION OF COMMITTEE.—Not later than October 1, 2022, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended.''.

(c) NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.—Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.), as amended by subsection (b), is further amended by inserting after section 2811B the following:

''SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.

''(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security, shall establish a national advisory committee to be known as the National Advisory Committee on Individuals with Disabilities and Disasters (referred to in this section as the 'Advisory Committee').

''(b) DUTIES.—The Advisory Committee shall—

''(1) provide advice and consultation with respect to activities carried out pursuant to section 2814, as applicable and appropriate;

''(2) evaluate and provide input with respect to the medical, public health, and accessibility needs of individuals with disabilities related to preparation for, response to, and recovery from all-hazards emergencies; and

''(3) provide advice and consultation with respect to State emergency preparedness and response activities, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary, in consultation with such other heads of agencies and departments as appropriate, shall appoint not more than 17 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.

''(2) REQUIRED MEMBERS.—The Advisory Committee shall include Federal members or their designees (who may be non-voting members, as determined by the Secretary) and non-Federal members, as follows:

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

''(B) The Administrator of the Administration for Community Living.

''(C) The Director of the Biomedical Advanced Research and Development Authority.

''(D) The Director of the Centers for Disease Control and Prevention.

''(E) The Commissioner of Food and Drugs.

''(F) The Director of the National Institutes of Health.

''(G) The Administrator of the Federal Emergency Management Agency.

''(H) The Chair of the National Council on Disability.

''(I) The Chair of the United States Access Board.

''(J) The Under Secretary for Health of the Department of Veterans Affairs.

''(K) At least 2 non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery.

''(L) At least 2 representatives from State, local, territorial, or tribal agencies with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

''(M) At least 2 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

''(d) MEETINGS.—The Advisory Committee shall meet not less frequently than biannually. At least one meeting per year shall be an in-person meeting.

''(e) DISABILITY DEFINED.—For purposes of this section, the term 'disability' has the meaning given such term in section 3 of the Americans with Disabilities Act of 1990.

''(f) COORDINATION.—The Secretary shall coordinate duties and activities authorized under this section in accordance with section 2811D.

''(g) SUNSET.—

''(1) IN GENERAL.—The Advisory Committee shall terminate on September 30, 2023.

''(2) RECOMMENDATION.—Not later than October 1, 2022, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended.''.

(d) ADVISORY COMMITTEE COORDINATION.—Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.), as amended by subsection (c), is further amended by inserting after section 2811C the following:

''SEC. 2811D. ADVISORY COMMITTEE COORDINATION.

''(a) IN GENERAL.—The Secretary shall coordinate duties and activities authorized under sections 2811A, 2811B, and 2811C, and make efforts to reduce unnecessary or duplicative reporting, or unnecessary duplicative meetings and recommendations under such sections, as practicable. Members of the advisory committees authorized under such sections, or their designees, shall annually meet to coordinate any recommendations, as appropriate, that may be similar, duplicative, or overlapping with respect to addressing the needs of children, seniors, and individuals with disabilities during public health emergencies. If such coordination occurs through an in-person meeting, it shall not be considered the required in-person meetings under any of sections 2811A(e), 2811B(e), or 2811C(d).

''(b) COORDINATION AND ALIGNMENT.—The Secretary, acting through the employee designated pursuant to section 2814, shall align preparedness and response programs or activities to address similar, dual, or overlapping needs of children, seniors, and individuals with disabilities, and any challenges in preparing for and responding to such needs.

''(c) NOTIFICATION.—The Secretary shall annually notify the congressional committees of jurisdiction regarding the steps taken to coordinate, as appropriate, the recommendations under this section, and provide a summary description of such coordination.''.

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 ability of personnel funded by programs authorized under this Act (including the amendments made by this Act) to participate in drills and operational exercises related to all-hazards medical and public health preparedness and response. Such drills and operational exercises may include activities that incorporate medical surge capacity planning, medical countermeasure distribution and administration, and preparing for and responding to identified threats for that region. Such personnel may include State, local, tribal, and territorial public health department or agency personnel funded under this Act (including the amendments made by this Act). 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 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)—

(A) 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

(B) 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.''; and

(2) by adding at the end the following:

''(f) PROTECTION OF NATIONAL SECURITY FROM THREATS.—

''(1) IN GENERAL.—In carrying out the duties under subsection (b)(3), the Assistant Secretary for Preparedness and Response shall implement strategic initiatives or activities to address threats, including pandemic influenza, that pose a significant level of risk to public health and national security based on the characteristics of such threat, which may also include a chemical, biological, radiological, or nuclear agent, including threats with a significant potential to become a pandemic. Such initiatives shall include activities to accelerate and support the advanced research, development, manufacturing capacity, procurement, and stockpiling of countermeasures, including initiatives under section 319L(c)(4)(F). Such activities may also include those related to readiness to respond to pandemic influenza threats by supporting the development and manufacturing of influenza virus seeds, clinical trial lots, and stockpiles of novel influenza strains.

''(2) AUTHORIZATION OF APPROPRIATIONS.—

''(A) IN GENERAL.—For purposes of carrying out this subsection, there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023.

''(B) SUPPLEMENT, NOT SUPPLANT.—Funds appropriated under this subsection shall be used to supplement and not supplant funds provided under section 319L(e) and section 319F–2(g).

''(C) DOCUMENTATION REQUIRED.—The Assistant Secretary for Preparedness and Response shall, as required under subsection (b)(7), document amounts expended for purposes of carrying out this subsection, including amounts appropriated to the Public Health and Social Services Emergency Fund under title II of Division H of the Consolidated Appropriations Act, 2018 (Public Law 115–141), as applicable to section 319L(c)(4)(F).''.

SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

(a) IN GENERAL.—Title XXVIII is amended by inserting after section 2811 of the Public Health Service Act (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) The Director of National Intelligence.

''(10) 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) Utilize a process to make recommendations to the Secretary regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization with respect to countermeasures, as defined in section 319F–2(c), including prioritization based on the health security needs of the United States. Such recommendations shall be informed by, when available and practicable, the National Health Security Strategy pursuant to section 2802, the Strategic National Stockpile needs pursuant to section 319F–2, and assessments 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 support alignment of countermeasure procurement with recommendations to address such needs under subparagraph (A).

''(C) Assist the Secretary in developing 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 or officials, as appropriate.''.

(b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—Section 2811(d) of the Public Health Service Act (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) IN GENERAL.—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 ''the Assistant Secretary for Preparedness and Response and'' after ''collaboration with'';

(B) by inserting ''and optimize'' after ''provide for'';

(C) 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

(D) 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 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 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 expiring or expired countermeasure, is a different countermeasure with the same indication that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

''(VII) a description of how such additions or modifications align with projected investments under previous countermeasures budget plans 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, which need not be provided in advance of procurement, that for each countermeasure procured 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 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;

(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;'';

(D) in subparagraph (G), by striking ''; and'' and inserting a semicolon;

(E) in subparagraph (H), by striking the period and inserting a semicolon; and

(F) by adding at the end the following:

''(I) ensure that each countermeasure or product under consideration for procurement pursuant to this subsection receives the same consideration regardless of whether such countermeasure or product receives or had received funding under section 319L, including with respect to whether the countermeasure or product is most appropriate to meet the emergency health security needs of the United States; and

''(J) provide assistance, including technical assistance, to maintain and improve State and local public health preparedness capabilities to distribute and dispense medical countermeasures and products from the stockpile, as appropriate.''; 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 toward 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 ability of the stockpile to meet emergency health security needs;

''(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;

''(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; and

''(ix) an assessment of whether the processes and procedures described by the Secretary pursuant to section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 are sufficient to ensure countermeasures and products under consideration for procurement pursuant to subsection (a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 319L, including with respect to whether such countermeasures and products are most appropriate to meet the emergency health security needs of the United States.

''(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) ADDITIONAL REPORTING.—In the first threat-based review submitted after the date of enactment of this Act pursuant to paragraph (2) of section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as amended by subsection (a), the Secretary shall include a description of the processes and procedures through which the Director of Strategic National Stockpile and the Director of the Biomedical Advanced Research and Development Authority coordinate with respect to countermeasures and products procured under such section 319F–2(a), including such processes and procedures in place to ensure countermeasures and products under consideration for procurement pursuant to such section 319F–2(a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), and whether such countermeasures and products are the most appropriate to meet the emergency health security needs of the United States.

(c) 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 ''$610,000,000 for each of fiscal years 2019 through 2023, to remain available until expended''.

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

(a) STRATEGIC INITIATIVES.—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 contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that 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, 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 diseases, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.''.

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

(1) by redesignating subsections (d), (e), and (f) as subsections (e), (f), and (g), respectively; and

(2) by inserting after subsection (c) the following new subsections:

''(d) EMERGING INFECTIOUS DISEASE PROGRAM.—

''(1) IN GENERAL.—The Secretary, acting through the Director of BARDA, shall establish and implement a program that supports—

''(A) advanced research and development activities for qualified pandemic or epidemic products; and

''(B) manufacturing infrastructure activities with respect to an emerging infectious disease.

''(2) FUNDING.—

''(A) IN GENERAL.—To carry out paragraph (1), there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023, to remain available until expended.

''(B) SUPPLEMENT NOT SUPPLANT.—Any funds provided to the Secretary under this paragraph shall be used to supplement and not supplant any other Federal funds provided to carry out paragraph (1).''.

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

Section 351A(k) of the Public Health Service Act (42 U.S.C. 262a(k)) 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) of the Public Health Service Act (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) in subparagraph (A)—

(A) in clause (ii), by striking ''; and'' and inserting '';''; and

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

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

''(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; and

''(v) potential deployment, distribution, and utilization of medical countermeasures; development of clinical guidance and emergency use instructions for the use of medical countermeasures; and, as applicable, potential post-deployment activities related to medical countermeasures;'';

(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) 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, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives''.

(b) CONTRACTING COMMUNICATION.—Section 319F–2(c)(7)(B)(ii)(III) of the Public Health Service Act (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, extend, or terminate such contract.''.

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) 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 ''$7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended''; and

(2) by striking the second sentence.

(b) THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—Subsection (e)(2) of section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), as redesignated by section 404(b), 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''.

SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTIBIOTIC RESISTANCE.

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

''SEC. 319E–1. ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA.

''(a) DEFINITIONS.—In this section:

''(1) ACTION PLAN.—The term 'Action Plan' means the Action Plan described in section 319E(a)(1).

''(2) ADVISORY COUNCIL.—The term 'Advisory Council' means the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria established by Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria).

''(3) NATIONAL STRATEGY.—The term 'National Strategy' means the National Strategy for Combating Antibiotic-Resistant Bacteria issued by the White House in September 2014, and any subsequent update to such strategy or a successor strategy.

''(b) ADVISORY COUNCIL.—The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria), including the National Strategy, and the Action Plan.

''(c) MEETINGS AND DUTIES.—

''(1) MEETINGS.—The Advisory Council shall meet as the Chair determines appropriate but not less than twice per year, and, to the extent practicable, in conjunction with meetings of the task force described in section 319E.

''(2) RECOMMENDATIONS.—The Advisory Council shall make recommendations to the Secretary, in consultation with the Secretary of Agriculture and the Secretary of Defense, regarding programs and policies intended to—

''(A) preserve the effectiveness of antibiotics by optimizing their use;

''(B) advance research to develop improved methods for combating antibiotic resistance and conducting antimicrobial stewardship, as defined in section 319E(h)(3);

''(C) strengthen surveillance of antibiotic-resistant bacterial infections;

''(D) prevent the transmission of antibiotic-resistant bacterial infections;

''(E) advance the development of rapid point-of-care and agricultural diagnostics;

''(F) further research on new treatments for bacterial infections;

''(G) develop alternatives to antibiotics for animal health purposes;

''(H) maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal health care providers; and

''(I) improve international coordination of efforts to combat antibiotic resistance.

''(3) COORDINATION.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the Antimicrobial Resistance Task Force established under section 319E(a) (commonly referred to as the 'Combating Antibiotic-Resistant Bacteria Task Force').''.

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 striking ''and platform technologies'' and inserting ''platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures''.

SEC. 602. UPDATING DEFINITIONS OF OTHER TRANSACTIONS.

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

(1) in subsection (a)(3), by striking '', such as'' and all that follows through ''Code'';

(2) in subsection (c)(5)(A)—

(A) in clause (i), by striking ''under this subsection'' and all that follows through ''Code'' and inserting ''(as defined in subsection (a)(3)) under this subsection''; and

(B) in clause (ii)—

(i) by amending subclause (I) to read as follows:

''(I) IN GENERAL.—To the maximum extent practicable, competitive procedures shall be used when entering into transactions to carry out projects under this subsection.''; and

(ii) in subclause (II)—

(I) by striking ''$20,000,000'' and inserting ''$100,000,000'';

(II) by striking ''senior procurement executive for the Department (as designated for the purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c))'' and inserting ''Assistant Secretary for Financial Resources''; and

(III) by striking ''senior procurement executive under'' and inserting ''Assistant Secretary for Financial Resources under''.

SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—The purpose of this section (including section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b)) is to support and advance 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 medical countermeasure master files, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'').

(b) MEDICAL COUNTERMEASURE MASTER FILES.—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) APPLICABILITY OF REFERENCE.—

''(1) IN GENERAL.—A person may submit data and information in a master file 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 by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

''(2) REFERENCE OF CERTAIN MASTER FILES.—In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed under section 571, such master file may be relied upon to help support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if such application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to such review and approval for such countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

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

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

''(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.

''(c) SPONSOR REFERENCE.—

''(1) IN GENERAL.—Each incorporation of data or information within a medical countermeasure master file shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such information within such master file without necessitating re-submission of such data or information. Master files shall be submitted in an electronic format in accordance with sections 512(b)(4), 571(a)(4), and 745A, as applicable, 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 person submitting an application for review 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.

''(d) ACKNOWLEDGEMENT OF THE RELIANCE UPON A MASTER FILE BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information 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.

''(2) CERTAIN APPLICATIONS.—If the Secretary has reviewed and relied upon specified data or information within a medical countermeasure master file to support the conditional approval of an application under section 571 to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how such data or information contained in such application meets the standards of evidence under subsection (c) or (d) of section 505, subsection (d) of section 512, or section 351 of the Public Health Service Act (as applicable) unless such disclosure includes any trade secret or confidential commercial information.

''(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this Act or section 351 of the Public Health Service Act (as such applicable Act is in effect on the day before 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;

''(2) alter the standards of evidence with respect to approval, licensure, or clearance, as applicable, of drugs, biological products, or devices under this Act or section 351 of the Public Health Service Act, including, as applicable, the substantial evidence standards under sections 505(d) and 512(d) or this Act and section 351(a) of the Public Health Service Act; or

''(3) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of data or information 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), 512(j), 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.

''(f) DEFINITIONS.—In this section:

''(1) The term 'master file holder' means a person who submits data and information to the Secretary with the intent to reference or authorize another person to reference such data or information to support a medical countermeasure submission, as described in subsection (a).

''(2) 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 section 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 a 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.

''(3) 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.''.

(c) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, 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 advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through 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 (b).

(d) GUIDANCE.—Not later than 2 years 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 (b) 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 advance the development or manufacture of security countermeasures, qualified countermeasures, and 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. 604. ANIMAL RULE REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the application of the requirements under subsections (c) and (d) of section 565 of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) (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 that 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 flexibility 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 decision-making 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, or 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.

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 nonprofit 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 that may result from utilization of genomic engineering technologies and related technologies for the purpose of compromising national health security.

(b) REPORT.—Not later than 270 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.

SEC. 606. REPORT ON VACCINES DEVELOPMENT.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing efforts and activities to coordinate with other countries and international partners during recent public health emergencies with respect to the research and advanced research on, and development of, qualified pandemic or epidemic products (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)). Such report may include information regarding relevant work carried out under section 319L(c)(5)(E) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)(E)), through public-private partnerships, and through collaborations with other countries to assist with or expedite the research and development of qualified pandemic or epidemic products. Such report shall not include information that may compromise national security.

SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR SAFETY AND HEALTH.

(a) REAUTHORIZATION OF MOSQUITO ABATEMENT FOR SAFETY AND HEALTH PROGRAM.—Section 317S of the Public Health Service Act (42 U.S.C. 247b–21) is amended—

(1) in subsection (a)(1)(B)—

(A) by inserting ''including programs to address emerging infectious mosquito-borne diseases,'' after ''subdivisions for control programs,''; and

(B) by inserting ''or improving existing control programs'' before the period at the end;

(2) in subsection (b)—

(A) in paragraph (1), by inserting '', including improvement,'' after ''operation'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (ii), by striking ''or'' at the end;

(II) in clause (iii), by striking the semicolon at the end and inserting '', including an emerging infectious mosquito-borne disease that presents a serious public health threat; or''; and

(III) by adding at the end the following:

''(iv) a public health emergency due to the incidence or prevalence of a mosquito-borne disease that presents a serious public health threat;''; and

(ii) by amending subparagraph (D) to read as follows:

''(D)(i) is located in a State that has received a grant under subsection (a); or

''(ii) that demonstrates to the Secretary that the control program is consistent with existing State mosquito control plans or policies, or other applicable State preparedness plans.'';

(C) in paragraph (4)(C), by striking ''that extraordinary'' and all that follows through the period at the end and inserting the following: ''that—

''(i) extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver; or

''(ii) the geographical area covered by a political subdivision or consortium for a grant under paragraph (1) has an extreme mosquito control need due to—

''(I) the size or density of the potentially impacted human population;

''(II) the size or density of a mosquito population that requires heightened control; or

''(III) the severity of the mosquito-borne disease, such that expected serious adverse health outcomes for the human population justify the waiver.''; and

(D) by amending paragraph (6) to read as follows:

''(6) NUMBER OF GRANTS.—A political subdivision or a consortium of political subdivisions may not receive more than one grant under paragraph (1).''; and

(3) in subsection (f)—

(A) in paragraph (1) by striking ''for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 through 2007'' and inserting ''for each of fiscal years 2019 through 2023'';

(B) in paragraph (2), by striking ''the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' and inserting ''this Act and other medical and public health preparedness and response laws''; and

(C) in paragraph (3)—

(i) in the heading, by striking ''2004'' and inserting ''2019''; and

(ii) by striking ''2004'' and inserting ''2019''.

(b) EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.—Section 2821 of the Public Health Service Act (42 U.S.C. 300hh–31) is amended—

(1) in subsection (a)(1), by inserting '', including mosquito and other vector-borne diseases,'' after ''infectious diseases''; and

(2) by amending subsection (b) to read as follows:

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $40,000,000 for each of fiscal years 2019 through 2023.''.

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

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

(b) 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''.

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

(d) 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) by 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)(A)—

(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) 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.

(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—Subsection (e)(1) of section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—

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

''(A) NON-DISCLOSURE OF INFORMATION.—

''(i) IN GENERAL.—Information described in clause (ii) shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

''(ii) INFORMATION DESCRIBED.—The information described in this clause is information relevant to programs of the Department of Health and Human Services that could compromise national security and reveal significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against chemical, biological, radiological, or nuclear threats, and is comprised of—

''(I) specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c);

''(II) information pertaining to the location security, personnel, and research materials and methods of high-containment laboratories conducting research with select agents, toxins, or other agents with a material threat determination under section 319F–2(c)(2); or

''(III) security and vulnerability assessments.'';

(2) by redesignating subparagraph (C) as subparagraph (D);

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

''(C) REPORTING.—One year after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and annually thereafter, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure, as well as the nature of any request under section 552 of title 5, United States Code that was denied using such authority.''; and

(4) in subparagraph (D), as so redesignated, by striking ''12'' and inserting ''17''.

SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.

Subsection (d) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended to read as follows:

''(d) DISCLOSURES.—No Federal agency may disclose under section 552 of title 5, United States Code any information identifying the location at which materials in the stockpile described in subsection (a) are stored, or other information regarding the contents or deployment capability of the stockpile that could compromise national security.''.

SEC. 703. CYBERSECURITY.

(a) STRATEGY FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE TO CYBERSECURITY THREATS.—

(1) STRATEGY.—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'') shall prepare and submit to the relevant committees of Congress a strategy for public health preparedness and response to address cybersecurity threats (as defined in section 102 of Cybersecurity Information Sharing Act of 2015 (6 U.S.C. 1501)) that present a threat to national health security. Such strategy shall include—

(A) identifying the duties, functions, and preparedness goals for which the Secretary is responsible in order to prepare for and respond to such cybersecurity threats, including metrics by which to measure success in meeting preparedness goals;

(B) identifying gaps in public health capabilities to achieve such preparedness goals; and

(C) strategies to address identified gaps and strengthen public health emergency preparedness and response capabilities to address such cybersecurity threats.

(2) PROTECTION OF NATIONAL SECURITY.—The Secretary shall make such strategy available to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Energy and Commerce of the House of Representatives, and other congressional committees of jurisdiction, in a manner that does not compromise national security.

(b) COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.—Subparagraph (D) of section 2811(b)(4) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(4)) is amended to read as follows:

''(D) POLICY COORDINATION AND STRATEGIC DIRECTION.—Provide integrated policy coordination and strategic direction, before, during, and following public health emergencies, with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan described in section 504(a)(6) of the Homeland Security Act of 2002 (6 U.S.C. 314(a)(6)), or any successor plan; and such Federal responses covered by the National Cybersecurity Incident Response Plan developed under section 228(c) of the Homeland Security Act of 2002 (6 U.S.C. 149(c)), including public health emergencies or incidents related to cybersecurity threats that present a threat to national health security.''.

SEC. 704. 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''.

(c) EMERGENCY USE INSTRUCTIONS.—Subparagraph (A) of section 564A(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is amended by striking ''subsection (a)(1)(C)(i)'' and inserting ''subsection (a)(1)(C)''.

(d) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b) is amended—

(1) in subparagraph (B), by inserting a comma after ''505''; and

(2) in subparagraph (C), by inserting ''or section 564A'' before the period at the end.

(e) TRANSPARENCY.—Section 507(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357(c)(3)) is amended—

(1) by striking ''Nothing in'' and inserting the following:

''(A) IN GENERAL.—Nothing in'';

(2) by striking ''disclose any'' and inserting ''disclose or direct—

''(i) any'';

(3) by striking the period and inserting ''; or''; and

(4) by adding at the end the following:

''(ii) in the case of a drug development tool that may be used to support the development of a qualified countermeasure, security countermeasure, or qualified pandemic or epidemic product, as defined in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act, any information that the Secretary determines has a significant potential to affect national security.

''(B) PUBLIC ACKNOWLEDGMENT.—In the case that the Secretary, pursuant to subparagraph (A), does not make information publicly available, the Secretary shall provide on the internet website of the Food and Drug Administration an acknowledgement of the information that has not been disclosed, pursuant to subparagraph (A).''.

SEC. 705. FORMAL STRATEGY RELATING TO CHILDREN SEPARATED FROM PARENTS AND GUARDIANS AS A RESULT OF ZERO TOLERANCE POLICY.

Not later than 14 days after the date of enactment of this Act, the Assistant Secretary for Preparedness and Response and the Assistant Secretary for the Administration on Children and Families shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a formal strategy to reunify with their parent or guardian, if the parent or guardian chooses such reunification, each child who—

(1) as a result of the initiative announced on April 6, 2018, and due to prosecution under section 1325(a) of title 8, United States Code;

(2) was separated from their parent or guardian and placed into a facility funded by the Department of Health and Human Services; and

(3) can be safely reunited with such parent or guardian.

SEC. 706. REPORTING RELATING TO CHILDREN SEPARATED FROM PARENTS AND GUARDIANS AS A RESULT OF ZERO TOLERANCE POLICY.

Beginning on the date of enactment of this Act, the Assistant Secretary for Preparedness and Response and the Assistant Secretary for the Administration on Children and Families shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate weekly reports on the status and welfare of the children who, as a result of the ''zero tolerance'' policy, were separated from their parent or guardian and are awaiting reunification with their parent or guardian, as well as the number of such children in facilities funded by the Department of Health and Human Services.

SEC. 707. TECHNICAL CORRECTION.

Section 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking ''subparagraph'' both places it appears in subclause (I) and subclause (II) and inserting ''paragraph''.

SEC. 708. SAVINGS CLAUSE.

Nothing in this Act shall be construed as reducing or limiting the authorities vested in any other Federal agency by any other Federal law.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Indiana (Mrs. BROOKS) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentlewoman from Indiana.

GENERAL LEAVE

Mrs. BROOKS of Indiana. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Indiana?

There was no objection.

Mrs. BROOKS of Indiana. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today to speak in support of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, known as PAHPA. I am proud to have introduced this important bill with Energy and Commerce Chairman GREG WALDEN, Ranking Member FRANK PALLONE, and my good friend Representative ESHOO, who is one of the original authors of the 2006 PAHPA bill and lead author of the last reauthorization in 2013.

This bipartisan public health and national security effort will ensure our Nation is better prepared to respond to natural disasters like hurricanes; emerging infectious diseases like Zika and Ebola; and chemical, biological, radiological, or nuclear attacks, whether from terrorist groups or from nation-states.

Seventeen years ago, Congress was the target of a biological attack when letters laced with anthrax arrived in Member offices just days or soon after the 9/11 terrorist attacks. In the aftermath of 9/11, the Blue Ribbon Study Panel on Biodefense was formed. It was led by bipartisan leaders: former Senator Joe Lieberman, former Governor Tom Ridge, and many others.

In October 2015, after extensive discussions around the country where they learned from experts, they created their ''National Blueprint for Biodefense,'' which provided us with a roadmap in drafting this important legislation.

I was the United States Attorney for the Southern District of Indiana during those 2001 anthrax attacks, and my own office dealt with an anthrax hoax when we received a letter with white powder inside. Of course, at the time, we didn't know it was a hoax. It was incredibly stressful for that staff member, who had to worry about their very own health. But that personal experience illustrated to me the importance of preparedness and sparked my interest in biodefense.

In the years since then, we know that the threat of a chemical, biological, radiological, or nuclear incident continues to grow. Every day, our adversaries are looking for more effective and faster ways to reduce the threat. It is not really a question of if we face the threat. It is a question of when.

Thanks to PAHPA and the 21st Century Cures Act, we are more prepared than ever for biological threats and attacks.

In July of just this last year, the FDA approved the first drug to treat smallpox. It is called TPOXX. But TPOXX isn't the only recent approval at the FDA. In July, the FDA also approved an autoinjector that provides a one-time dose of an antidote to block effects of a nerve agent. This new antidote and TPOXX will help protect Americans from biological attacks.

But PAHPA is much more than just a biodefense bill. It also ensures a coordinated healthcare response, whether to hurricanes or other natural disasters.

Florence has just hit the East Coast and residents in both North and South Carolina are still recovering and dealing with ongoing flooding. During the 2017 hurricane season, whether it was Hurricane Harvey, Irma, Jose, or Maria, far too many Americans were killed. It showed us that we need to do better to prioritize the needs of every person in our communities.

The PAHPA bill we are considering today does just that. It prioritizes our Nation's most vulnerable populations: our children, senior citizens, and those with disabilities. It reauthorizes the advisory committee focused on the specific needs of children and creates new advisory committees to ensure the needs of the elderly and those with disabilities are considered.

The bill provides liability protections for healthcare professionals who volunteer after medical disasters. In addition to these types of Good Samaritan provisions, the bill ensures more healthcare professionals like nurses, doctors, and others can be hired and trained when facing a public health crisis by strengthening our National Disaster Medical System, which provides grants to our regional healthcare network.

It also ensures we have a robust supply of vaccines and basic equipment like gloves, hazmat suits, masks, personal protective gear, and more in our strategic national stockpiles located all across the country, so that our healthcare professionals and first responders have what they need.

PAHPA ensures our preparedness and response capabilities will include a robust pipeline of medical countermeasures by reauthorizing and increasing funding for the BioShield Special Reserve Fund and BARDA, the Biomedical Advanced Research and Development Authority.

BARDA's work over the last decade has resulted in FDA approvals for more than 42 different medical countermeasures. The development of medical countermeasures is a lengthy and often risky endeavor, which is why sending a clear signal that BARDA remains a strong and committed partner with academic institutions and the private sector in these efforts is so very important.

Last week, we saw even another example of a success of research funded by BARDA when FDA approved a product called ReCell, the first spray-on skin product ever approved for use in the United States. This new treatment will help treat burn victims so they can heal faster and with less risk of infection from painful skin grafts. By using a piece of a patient's skin about the size of a credit card, a doctor can turn it into a single cell-based solution that can be sprayed over the patient's burns so that new skin can grow and replace the damaged skin.

These types of investments BARDA is making into innovative research are critical, but it is also important that we continue to address threats that have been around for years.

It has been 100 years since the 1918 pandemic influenza killed millions of people around the globe, including 675,000 Americans. Some experts predict that we are actually due for the potential of another global pandemic influenza.

To address that threat, the bill we are considering today authorizes $250 million for the Assistant Secretary for Preparedness and Response, the ASPR, to address threats like pandemic influenza. Specifically, the bill directs the ASPR to work to increase manufacturing capacity and stockpile medical countermeasures.

While the PAHPA bill we are considering today authorizes funding for research into known threats like pandemic influenza, it also maintains the flexibility that is the foundation of our medical countermeasure enterprise to deal with unknown threats for which we may have no defense today.

Even today, the Democratic Republic of the Congo continues to deal with an ongoing Ebola outbreak. In order to ensure we are better prepared when we face an outbreak like Ebola or Zika, the bill we are considering today does three important things.

First, it improves the existing emergency response fund so that the Secretary of Health and Human Services does not have to wait on approval from Congress to immediately fund response measures needed to contain an outbreak and save lives. This emergency response fund will create a bridge so that immediate funding is available, so we can then supplement with an emergency appropriations bill later.

Secondly, the bill requires GAO to conduct a review of the emergency response fund to help appropriators decide what funding levels and resources are needed.

The third thing the bill does to help address threats like Ebola and Zika is to authorize $250 million in funding for an emerging infectious disease program so that BARDA can invest in new research.

The PAHPA bill reauthorization we are considering is the process of months of committee work in both the House and the Senate, and I want to thank all the staff members and all of the organizations, everyone who has been involved, and all the Members who have participated, whether it is subcommittee or committee hearings on this bill, examining our response to threats. I thank everyone involved for their dedication and commitment to

making sure we have the procedures, resources, and support in place to protect our fellow citizens from public health and national security threats.

I can't emphasize enough how critically important it is to reauthorize PAHPA. We have a duty as Members of Congress to keep Americans safe and secure. This bill is an essential component of accomplishing that goal. I urge all Members to support this critical bipartisan piece of legislation.

Mr. Speaker, I include in the RECORD letters from many organizations that support the bill.

ADULT VACCINE ACCESS COALITION,
July 23, 2018.

Hon. SUSAN W. BROOKS,
Member of Congress,
Washington, DC.
Hon. ANNA ESHOO,
Member of Congress,
Washington, DC.

DEAR REPRESENTATIVES BROOKS AND ESHOO: On behalf of the Adult Vaccine Access Coalition (AVAC), we are pleased to express our support for bipartisan legislation that recently passed the House Energy and Commerce Committee, ''Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPA) of 2018''.

AVAC includes more than fifty organizational leaders in health and public health who are committed to raising awareness of and engaging in advocacy on the importance of adult immunization. AVAC priorities and objectives are driven by a consensus process with the goal of enabling stakeholders to have a voice in the effort to improve access to and utilization of adult immunizations.

The bipartisan reauthorization of the PAHPA provides improvements to key preparedness and response programs, enhances personnel and hiring authorities, as well as prioritizes cybersecurity in health care and provides necessary resources for the development of medical countermeasures for pandemic influenza and emerging infectious diseases. We are delighted the Managers' Amendment included references to immunization programs and immunization information systems under Section 319D. These additions will help to strengthen and enhance coordination and integrate immunization programs and immunization information systems (IIS) capabilities into public health emergency preparedness, planning, and response activities.

Immunization Information Systems (IIS), or registries, confidential, population-based, computerized systems can record immunization doses administered by participating providers to persons residing within a given jurisdiction. They provide state and local public health agencies aggregate data on immunization coverage rates for disease surveillance and program operations. IIS' can serve as a vital component for emergency preparedness and response activities and are an optimal tool for use during a pandemic or other emerging infectious disease event by enabling communication with providers, identifying variations in access and utilization of immunization, and enabling implementation of targeted strategies during emergency preparedness and response activities.

Congratulations on putting together a strong, bipartisan reauthorization package that reflects many of the important priorities shared by stakeholders. We look forward to working with you throughout the process to enact the 2018 Pandemic and All-Hazards Preparedness Reauthorization Act.

Sincerely,

LISA FOSTER,
AVAC Manager.
ABBY BOWNAS,
AVAC Manager.

ALLIANCE FOR BIOSECURITY,
U.S. CHAMBER OF COMMERCE,
July 27, 2018.

TO THE MEMBERS OF THE U.S. HOUSE OF REPRESENTATIVES: On behalf of the Alliance for Biosecurity and the U.S. Chamber of Commerce, we support H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and urge the House to pass this bipartisan legislation before the Pandemic and All-Hazards Preparedness Act (PAHPA) expires at the end of September 2018. H.R. 6378 is central to protecting American citizens, organizations, and communities against natural and manmade biosecurity hazards.

H.R. 6378 would authorize crucial funding for the Project BioShield Special Reserve Fund and Biomedical Advanced Research and Development Authority (BARDA). However, we urge policymakers to account for inflation to ensure that future spending levels adequately support the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and implementation Plan, the BARDA Strategic Plan, and related efforts.

H.R. 6378 would establish several important programs within BARDA, especially a Pandemic Influenza Program to support research and development activities to enhance responses to pandemic influenza and an Emerging Infectious Disease Program to monitor and address infectious diseases that could cause a deadly pandemic. Both programs would be funded at $250 million per year through FY 2023.

The bill would also create new and sustainable market-based incentives to advance cutting-edge biomedical research. Our groups support developing strategic partnerships between BARDA and the business community to mitigate threats that could pose a significant risk to U.S. health and safety.

Reauthorizing PAHPA would also help ensure the sustainability of the medical countermeasures enterprise by transferring the authority that governs the procurement of medical countermeasures from the Centers for Disease Control and Prevention (CDC) to the Office of the Assistant Secretary for Preparedness and Response (ASPR).

The legislation would codify ASPR's role in coordinating Strategic National Stockpile operations with CDC. We also believe that such teamwork would make the U.S. better equipped to tackle public health emergencies and natural disasters.

We urge the full House to swiftly consider and pass H.R. 6378.

Sincerely,

THE HONORABLE JACK KINGSTON,
Secretariat, Alliance for Biosecurity.
NEIL L. BRADLEY,
Executive Vice President and Chief Policy Officer, U.S. Chamber of Commerce.

ALLIED BIOSCIENCE,
Plano, TX, July 23, 2018.

Hon. SUSAN BROOKS,
Member of Congress,
Washington, DC.

DEAR REPRESENTATIVE BROOKS: I write to thank you for a provision in your recently introduced legislation, H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. This provision updates the authorization for the Biomedical Advanced Research and Development Authority (BARDA) to include the mitigation of infectious disease. This provision will make our nation safer.

Allied BioScience (ABS) has engaged BARDA with ideas for collaboration that have the potential to enhance the biological safety of our nation by combating antimicrobial resistance through environmental intervention. Under the existing authorization, BARDA is limited to developing pharmacological interventions. This limitation precludes collaboration at this time. Your legislation amends the definition of ''qualified pandemic or epidemic products'' to include ''a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure an infectious disease (as defined in section 319F–1(a)(2))''. This change would create a path forward to collaborate to develop novel solutions to antimicrobial resistance that will provide a safer nation.

ABS has developed a semi-permanent antimicrobial coating that creates a long-lasting barrier to microbial growth. In clinical trials, ABS's coating, when applied in an ICU setting has shown to reduce the presence of Multi-Drug Resistant Organisms (MDROs) by up to 70% with an efficacy of at least four months per application. Comparable reductions in Hospital Acquired Infections have seen a corresponding reduction. Reduction in rates of infection decreased the need to treats MDRO's and breaks the cycle of mutation that creates increasingly potent ''superbugs''. Our research demonstrates that environmental mitigation is a key component to addressing antimicrobial resistance.

Thank you again for your efforts to modernize BARDA to provide the flexibility needed to combat ever-evolving threats. We enthusiastically support H.R. 6379, and look forward to its swift passage and enactment into law. If you have any questions about ABS I would be happy to talk further with you at your convenience.

Sincerely,

MIKE RULEY,
CEO.

AMERICAN ASSOCIATION OF BLOOD BANKS, AMERICA'S BLOOD CENTERS, AMERICAN RED CROSS,
July 25, 2018.

Hon. GREG WALDEN,
Chairman, House Energy and Commerce Committee, Washington, DC.
Hon. SUSAN BROOKS,
House of Representatives,
Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy and Commerce Committee, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives,
Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, AND REPRESENTATIVES BROOKS AND ESHOO: AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross commend the House Energy and Commerce Committee's commitment to improving the nation's preparedness and response capabilities through the reauthorization of the Pandemic and All-Hazards Preparedness Advancing Innovation Act (PAHPAIA) of 2018 (H.R. 6378). Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

We would like to especially highlight two sections of the bill important to us and our collective members:

Section 116 is a significant step in examining the unique, and often overlooked, role of the nation's blood supply in emergency

preparedness and response systems and the specific challenges associated with donor recruitment, implementation of safety mandates and innovation, and adequacy in the face of public health emergencies. We believe that policies that support the availability of a safe and adequate blood supply are needed. The report required by this section is critical to evaluating possible solutions.

We strongly support the Committee's specific recognition of the blood supply in Section 207, which requires the Assistant Secretary for Preparedness and Response (ASPR) to develop guidelines for regional health care emergency and response systems. We support the provision that requires the ASPR to consult with blood banks and other key stakeholders when developing and updating guidelines. Including blood centers in this process is paramount and consistent with the Department of Health and Human Services' (HHS) recognition of blood as one of the core functional areas in Emergency Support Function #8 of the National Response Framework. We also commend the Committee for recognizing potential financial implications for blood centers to implement and follow the guidelines. Given that blood is an essential part of the nation's trauma system, emergency preparedness and response system and healthcare system generally, it is essential that financial barriers not impede the availability of safe blood ahead of and during response activities.

AABB, America's Blood Centers and the American Red Cross welcome the opportunity to work with the Committee to ensure that these important provisions promoting the safety and availability of the U.S. blood supply remain during conference negotiations with the Senate.

MARY BETH BASSETT,
President, AABB.
KATE FRY,
Chief Executive Officer, America's Blood Centers.
JAMES C. HROUDA,
President, Biomedical Services, American Red Cross.

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS,
July 18, 2018.

Hon. SUSAN BROOKS,
Washington, DC.
Hon. GREG WALDEN,
Washington, DC.
Hon. ANNA ESHOO,
Washington, DC.
Hon. FRANK PALLONE,
Washington, DC.

DEAR REPRESENTATIVES BROOKS, ESHOO, WALDEN, AND PALLONE: On behalf of the American College of Emergency Physicians (ACEP), our 38,000 members, and the more than 140 million patients we treat each year, I am writing to express ACEP's support for H.R. 6378, the ''Pandemic and All-Hazards Preparedness and Advancing Innovation (PAHPAI) Act of 2018.''

In particular, ACEP appreciates your legislation's focus on improving regionalized emergency preparedness and response systems, inclusion of the MISSION ZERO Act's provisions to facilitate the use of military trauma teams in civilian trauma centers, and the addition of Good Samaritan liability protections for health care professionals who volunteer during federally-declared disasters.

Regionalized systems for emergency care response are vital to ensuring patients are transported and treated in the most appropriate setting. While it is important to maximize our resources and capabilities on a daily basis, it becomes imperative when health care providers respond to a natural or man-made disaster. We would like to thank you for emphasizing the establishment and enhancement of these systems, especially the demonstration program designed to improve medical surge capacity, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across states, territories, and regional jurisdictions.

ACEP is very supportive of the trauma system improvements included in H.R. 6378, specifically the grants for military-civilian partnerships in trauma care as established in the MISSION ZERO Act (H.R. 880). ACEP believes this policy serves three purposes. First, it makes additional trauma care personnel available to treat severely injured civilian patients. Second, it allows military trauma teams to maintain their skills in between rotations to conflict areas. Third, it allows trauma team members to train together so that when they are deployed, everyone performs his/her duties in a coordinated manner with the other members, thereby improving care to injured military personnel.

The Good Samaritan liability protections established in this legislation will help encourage availability of health care professionals during times of disaster, which can be crucial to supplementing the efforts of emergency physicians and the Disaster Medical Assistance Teams (DMATs) on-site. ACEP believes volunteers responding to a disaster, whether declared by the President of the United States or the Secretary of the U.S. Department of Health and Human Services (HHS), should be protected from liability while they are providing care within the scope of their expertise and are acting in good faith. We appreciate your efforts to include this essential provision in H.R. 6378.

Other aspects of the legislation that are important to emergency physicians and will help ensure the nation is prepared to contend with all disasters and unexpected emergencies include your provisions to improve the National Disaster Medical System (NDMS); expand public health surveillance; study DMAT readiness capabilities; improve the Public Health Emergency Fund (PHEF); strengthen the Healthcare Preparedness and Response Program (HPRP), formerly the Hospital Preparedness Program (HPP); extend authorization for the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP); and study hospital preparedness capabilities. ACEP would also like to commend you on your oversight of the Assistant Secretary for Preparedness and Response's (ASPR) efforts to reunify children who were separated from their parent or guardian (due to the ''zero tolerance'' policy) and placed into the custody of HHS.

Finally, we would once again urge the Committee and the Congress to ensure sufficient funding is provided for the PHEF, HPRP, NDMS, and Medical Reserve Corps (MRC) to ensure their effectiveness and we encourage you to seek a sufficient, guaranteed federal funding stream. Without a dedicated and appropriate amount of federal resources for these critical programs, we are greatly concerned that the nation as a whole, and emergency medical providers specifically, will not have the infrastructure, personnel, or tools necessary to provide optimal care during a natural or man-made disaster or infectious disease outbreak.

Sincerely,
PAUL D. KIVELA, MD, MBA, FACEP,
ACEP President.

AMERICAN COLLEGE OF SURGEONS,
July 20, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, Committee on Energy and Commerce, Washington, DC.

DEAR CHAIRMAN WALDEN AND RANKING MEMBER PALLONE: On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we would like to express our support for the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI), H.R. 6378. We appreciate the work the Energy and Commerce Committee has accomplished to incorporate important improvements to trauma care and begin the process for establishing the framework for a trauma system that can fully meet the needs of any disaster and provide the highest-quality health care.

ACS is particularly appreciative of the inclusion of the Mission Zero Act, H.R. 880 in the PAHPAI. Establishing and maintaining high-quality and adequately-funded trauma systems throughout the United States, including within the Armed Forces, is a priority of the ACS and our Committee on Trauma (COT). The Mission Zero Act authorizes $15 million in grant funding to assist civilian trauma centers in partnering with military trauma professionals and creates a pathway to provide patients with excellent trauma care in times of peace and conflict. In addition, this legislation requires utilization of trauma data reporting as a requirement for the grant program. The measuring and recording of data is a cornerstone of advancing not only trauma care, but health care as a whole. Overall, the Mission Zero Act is a critical step toward achieving the goal of zero preventable injury deaths after injury.

Inclusion of the Good Samaritan Health Professionals Act, H.R. 1876, which is legislation that would reduce barriers for health care providers looking to volunteer during a federally-declared disaster, is a welcome addition to PAHPAI. This section in PAHPAI will help to greatly decrease loss of life as well as improve outcomes during federally declared public health emergencies.

We also applaud the Committee for highlighting the critical issue of improving our trauma care system by including language creating a demonstration project promoting a regionalized approach to disaster response. Trauma systems have been organized across the country to manage the time-sensitive crises of acutely injured patients in an efficient manner on a daily basis. Trauma systems span the continuum of care including prior to the point of injury and through rehabilitation. As a result, these systems engage in numerous activities aimed at improving care and outcomes, including bystander training, emergency medical services (EMS) training and coordination, hospital preparedness, injury prevention efforts, and continuous quality improvement. All of these activities will assist with responding to public health emergencies such as biological, radiological, nuclear events, and other mass casualty incidents.

The ACS believes the PAHPAI represents significant progress in the process of ensuring that trauma systems, centers, and health care providers are able to meet the needs of all Americans. We thank you for your leadership on this significant legislation and stand ready to work with you toward final passage in the House.

Sincerely,
DAVID B. HOYT, MD, FACS,
Executive Director, American College of Surgeons.

Mrs. BROOKS of Indiana. Mr. Speaker, I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC, September 24, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy & Commerce, Washington, DC.

DEAR CHAIRMAN WALDEN: I write concerning H.R. 6378, the ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''. This legislation includes matters that fall within the Rule X jurisdiction of the Committee on Homeland Security.

In order to expedite floor consideration of H.R. 6378, the Committee on Homeland Security will forgo action on this bill. However, this is conditional on our mutual understanding that forgoing consideration of the bill would not prejudice the Committee with respect to the appointment of conferees or to any future jurisdictional claim over the subject matters contained in the bill or similar legislation that fall within the Committee's Rule X jurisdiction. I request you urge the Speaker to name members of the Committee to any conference committee names to consider such provisions.

Please place a copy of this letter and your response acknowledging our jurisdictional interest in the Congressional Record during House Floor consideration of the bill. I look forward to working with the Committee on Energy and Commerce as the bill moves through the legislative process.

Sincerely,

MICHAEL T. MCCAUL,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, September 24, 2018.

Hon. MICHAEL T. MCCAUL,
Chairman, Committee on Homeland Security, Washington, DC.

DEAR CHAIRMAN MCCAUL: Thank you for your letter concerning H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and I appreciate your willingness to forgo action on the bill.

I agree that forgoing consideration of the bill should not prejudice the Committee on Homeland Security with respect to the appointment of conferees or to any future jurisdictional claim over the subject matters contained in the bill or similar legislation that fall within the Committee's Rule X jurisdiction. I will request that the Speaker name members of the Committee to any conference committee to consider such provisions.

Finally, I will place a copy of your letter and this response into the Congressional Record during consideration of the measure on the House floor.

Sincerely,

GREG WALDEN,
Chairman.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 6378, the Pandemic All-Hazards Preparedness and Advancing Innovation Act of 2018. I want to thank Chairman WALDEN and Representatives ESHOO and BROOKS, as well as all the staff, for their hard work on this bill. Together, we have ensured a robust product that reflects priorities for Members on both sides of the aisle and the agencies responsible for ensuring our emergency preparedness.

This is a vitally important public health bill that ensures that we can prepare for and respond to health security events like bioterrorism, emerging infectious diseases, and natural disasters. It will support the development of new treatments and the stockpiling of medications and supplies that will be deployed to communities nationwide in the case of an emergency.

As we all know, effectively preparing for and responding to these events requires extensive coordination between Federal, State, local, and Tribal governments, as well as private sector organizations across the country.

This bill reauthorizes or establishes critical programs that will help us better prepare and respond to any major health emergency.

Let me discuss some of the specifics of how this bill will help us do that.

It reauthorizes a loan repayment program that would help to strengthen and grow our public health workforce. This is critically important, as we are still trying to dig out of a public health funding hole that began during the Great Recession.

This bill also makes a technical update to the Hospital Preparedness Program to reflect the use of the term ''coalition'' instead of ''partnership'' by grantees and other stakeholders. This language change is not intended to make changes related to the current cooperative agreement structure, nor does it intend to alter the role and responsibilities of States, territories, and directly funded cities, which are awardees of funding under the Hospital Preparedness Program.

Therefore, it continues to require that the Centers for Disease Control and Prevention, the CDC, provide funding through cooperative agreements to States, territories, and cities to support healthcare coalitions in their communities through the Hospital Preparedness Program.

□ 1515

The bill also amends the Public Health Emergency Preparedness Program to require public health departments to partner with nursing homes and hospitals to promote and improve public health preparedness and response.

It also requires public health departments to work with utility companies and other critical infrastructure partners to help ensure that electricity and other critical infrastructure will remain functioning or return to function as soon as practicable after a public health emergency.

Both of these requirements are intended to help prevent another tragedy like the tragic deaths that occurred at a Florida nursing home last year in the aftermath of Hurricane Irma.

Mr. Speaker, this bill also updates the authorization for the public health emergency rapid response fund so we can prevent any delay in HHS' rapid response to public health emergencies in the future.

It also maintains the administration's flexibility to determine the best placement for the Strategic National Stockpile, or SNS. I have concerns with moving the SNS from the direction of the Centers for Disease Control and Prevention to the Assistant Secretary for Preparedness and Response. To date, I have yet to hear a strong argument in support of this move.

I also believe CDC has the relationships and expertise that make the most sense for managing and operationalizing the stockpile. The CDC also has a record of successful stewardship of the SNS. That is why I supported the increased transparency and reporting included in this bill.

Wherever the Strategic National Stockpile is placed, it is critical that we ensure that our current preparedness and response capabilities are not weakened by its placement.

I also want to highlight two provisions that were included that will ensure Congress receives the information it needs to respond to the Trump administration's family separation crisis. The Assistant Secretary for Preparedness and Response will be required to submit to the Energy and Commerce Committee a formal strategy on their family reunification efforts as well as keep the committee informed on the status of the children still awaiting reunification.

The Trump administration's cruel zero-tolerance policy resulted in a manmade crisis that has impacted the lives of thousands of parents and children. While we can't undo the damage done by this policy, these provisions ensure that Congress has the information it needs to help reunite each child with their family and make sure this never happens again.

Furthermore, while these provisions are important, they should not take the place of an actual oversight hearing on this cruel policy. This is something committee Democrats have repeatedly requested, and we will continue to do so.

Finally, Mr. Speaker, overall, I want to say this is a good bill. Our national preparedness and response capabilities will be better prepared to respond to public health threats thanks to the passage of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

Mr. Speaker, I urge my colleagues to support H.R. 6378, and I reserve the balance of my time.

Mrs. BROOKS of Indiana. Mr. Speaker, I yield 5 minutes to the gentleman from Oregon (Mr. WALDEN), the chairman of the Energy and Commerce Committee.

Mr. WALDEN. Mr. Speaker, I rise today, obviously, in support of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

I want to thank my friend and colleague from New Jersey (Mr. PALLONE), our ranking Democrat on the committee, for working with me on this effort, but especially I want to thank Representative BROOKS from Indiana for her tireless effort and the partnership of my friend, Representative ANNA ESHOO of California. She and Mrs.

BROOKS really did the heavy lift here for the committee on this effort. They were able to shepherd this critical reauthorization to the floor today with unanimous support both in the subcommittee and in the full committee.

So, for those out there who are watching our proceedings, know that actually we do work together and we do get some really important public policy done.

These programs, commonly known as PAHPA, enable critical partnerships between the Federal Government, State and local authorities, and the private sector to ensure our Nation is responsibly prepared for and able to respond to public health emergencies. It is time that we get it right; it is critical that we get it right; and we are.

It is not really a matter of if, but when, the next pandemic strikes. The projections simply are horrifying. A full-blown pandemic flu outbreak could literally kill millions of people within months—within months. We must have the tools, backed by stable and predictable funding, to respond to these threats and especially to the threat of pandemic flu.

With this vote, the House will take an important step toward keeping our families safe in the worst-case scenarios of dangerous disease outbreak or in the case of chemical or biological attack. We are moving this reauthorization on time and in a bipartisan fashion.

Like my colleague from Indiana, I remember when anthrax was sent to our offices and to the postal facility, and loss of life and illness and concern, and we all wondered what is next. That was part of what prompted us to get to this point and pass this legislation, not only today but back then.

This is really important work, Mr. Speaker, and I commend my colleagues and the staff, who really do the incredible work to help us get it right. This is legislation now that will head over to the Senate, where I hope they will give it the same due consideration that we are about to here today, and then get this down to President Trump's desk, where he will sign it into law.

Mr. Speaker, I want to again thank my colleagues and staff on both sides of the aisle.

Mr. PALLONE. Mr. Speaker, I have no additional speakers, and I reserve the balance of my time.

Mrs. BROOKS of Indiana. Mr. Speaker, I yield 5 minutes to the gentleman from Texas (Mr. BURGESS), the subcommittee chair for the Subcommittee on Health.

Mr. BURGESS. Mr. Speaker, I thank the gentlewoman for yielding.

Mr. Speaker, one century ago, our country was in the midst of the worst pandemic in history. It claimed the lives of almost 700,000 Americans and killed more than 50 million people worldwide.

Mr. Speaker, we listened to testimony; we discussed aspects of this legislation before us today; and it is critical that we remember the significance of the centennial anniversary of the 1918 influenza pandemic as we consider this legislation today.

The creation of the Assistant Secretary for Preparedness and Response under the original legislation of 2006 has helped us to make monumental strides in preparedness, coordination, and response. Close collaboration between the Centers for Disease Control and the Food and Drug Administration and our State, local, and territorial public health partners has been vital in making this progress.

Much like politics, much of public health is local and executed on the ground by our hospitals, our health departments, and our emergency responders, who are our front lines in addressing infectious diseases, disasters, and threats.

We must evaluate the domestic biological surveillance systems, such as BioWatch. This bill will help bring those programs up to date so they are operating with the most efficient capabilities and technologies. We must also look for innovative ways to continue to advance our medical countermeasures and ensure that Americans can access the medications that will provide critical protection in the future.

As we consider the problem of antimicrobial resistance in this country, we must discuss new methods to curb this growing problem.

It is important to note that this reauthorization bill is being heard on the floor of the House prior to the expiration of the fiscal year, at which time the current authorization expires. The House, once again, has done its work in this regard, and we do urge our counterparts in the Senate to do their work as well.

This reauthorization includes an important provision: The MISSION ZERO Act. The MISSION ZERO Act seeks to connect American patients with battle-tested trauma care through the craft of military trauma care providers. The bill provides grants to allow military trauma care providers and teams to offer care in our Nation's leading trauma centers and systems.

The need for top-notch trauma care extends across our Nation, far away from the battlefield. I first introduced this bipartisan bill with my fellow Texan, Representative GENE GREEN, following a police shooting in Dallas 2 years ago.

Over 2 years ago, five police officers were killed and nine more were injured in a shooting in downtown Dallas. In the immediate aftermath of the attack, area hospitals sprung into action and activated their disaster plans. The staff at Parkland Hospital, Baylor University Hospital, and other medical professionals provided excellent emergency care to victims of the attack.

Frontline facilities and responders in Dallas experienced this firsthand in 2014 when a patient presented with Ebola to a Dallas-Ft. Worth emergency department.

We must remember that infectious diseases are a mere plane ride away, and we must continue to ensure that we are prepared and ready to respond to emerging infectious diseases worldwide.

This Pandemic and All-Hazards Preparedness Reauthorization Act is critical to protecting the lives of Americans and providing the necessary tools and infrastructure when disaster strikes.

I want to thank Representative SUSAN BROOKS and ANNA ESHOO for their work on this legislation before us today. Mr. Speaker, I strongly support this legislation, and I urge my colleagues to do the same.

Mrs. BROOKS of Indiana. Mr. Speaker, I yield 1 minute to the gentleman from Florida (Mr. BILIRAKIS), who also serves on the Subcommittee on Health.

Mr. BILIRAKIS. Mr. Speaker, I want to thank Congresswoman BROOKS, who is doing an outstanding job. We both served on the House Committee on Homeland Security, and we chaired a subcommittee prior to Energy and Commerce. She is doing an outstanding job.

Mr. Speaker, I rise today in strong support of H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

From storm-related injuries and illnesses to delivery and logistics issues, last year's historically costly hurricane season tested the mettle of our health delivery system, and I am pleased to see children, seniors, and other at-risk patient communities being addressed in this reauthorization.

This bill also encourages innovative partnerships and coalitions, like the Nicklaus Children's Hospital and the Florida International University, to continue to develop novel approaches to healthcare delivery and, ultimately, save lives.

Mr. Speaker, I urge my colleagues to support this critical piece of legislation.

Mr. PALLONE. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I want to again thank all my colleagues on both sides of the aisle for moving and working on this legislation.

Mr. Speaker, I urge my colleagues to support H.R. 6378, and I yield back the balance of my time.

Mrs. BROOKS of Indiana. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I would like to particularly thank Dr. BURGESS and the ranking member of the Subcommittee on Health, GENE GREEN, for their leadership in working with so many of us who have brought this legislation to the floor at this time.

It is really so very critical that all relevant Federal agencies, particularly the leadership of CDC and the ASPR, work together with our local and State partners that are truly on the ground; and I certainly urge my colleagues to

pass this important piece of legislation not only to ensure that public health is of paramount importance in this country, but, also, because this is an incredibly important piece of national security legislation.

Mr. Speaker, I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, I rise in support of this bipartisan legislation, the Pandemic and All-Hazards Preparedness and Innovation Act and I'm very proud to have Representative SUSAN BROOKS as my partner. This legislation is the product of negotiation and compromise between the House and the Senate and I'm pleased that my colleagues were able to reach agreement on a bill that ensures our nation is prepared to respond to a wide range of public health emergencies, whether man-made or occurring through a natural disaster or infectious disease.

In 2001 our nation endured the horrific attacks on September 11th and the anthrax attacks that followed shortly thereafter. Congress realized that our country was not prepared to coordinate responses to mass casualty events or chemical attacks, and in 2006, I wrote legislation with then-Representative RICHARD BURR to address these shortfalls. That important legislation, the original Pandemic and All-Hazards Preparedness Act, was signed into law the same year.

The Pandemic and All-Hazards Preparedness and Innovation Act we're considering today is critical to our national security. The legislation updates the original PAHPA by directing federal agencies to respond to new and emerging threats, and strengthens our nation's existing preparedness and response programs. The reauthorization meets the challenges that we face today and those we anticipate facing in the future.

Events over the past few years including Zika, the reemergence of Ebola, and the constant looming threat of a biological attack by another nation or hostile non-state enemies underscore the real threats our country continues to face. In 2017, our nation experienced the most destructive hurricane season in recent memory, followed quickly by the most deadly flu season in decades. This year, parts of our country have already faced devastating hurricanes and the season is not over yet. Our experience with each of these hazards reminds us that our country is not yet adequately prepared to deal with potentially devastating widespread public health crises. That's why this legislation is so critical.

The legislation provides the authorization and federal resources to invest in programs that allow the Biomedical Advanced Research and Development Authority to maintain its nimble and flexible framework while responding to the existing and emerging threats our country may face. It also directs BARDA to address antimicrobial resistance which is critical to our nation's biodefense If we have a chemical or biological attack that leaves individuals with burns or open wounds, the medical countermeasures BARDA has developed to treat that attack will be useless if those injured contract secondary antibiotic resistant infections.

BARDA was created by my original legislation and has been extremely successful in investing in drugs that are needed to be stockpiled, and where the federal government is the only customer. There is no other market for these products and that's why BARDA is so important. BARDA has worked with over 190 partners and brought 35 medical countermeasures through research and development to FDA approval No private company has a track record that compares to what BARDA has accomplished in just over 10 years.

This bill restores multiyear appropriations for the Project BioShield Special Reserve Fund. My original legislation provided advanced appropriations for Project BioShield for the purpose of accelerating the research, development, purchase, and availability of effective medical countermeasures against biological, chemical, radiological, and nuclear (CBRN) threats. Restoring multiyear appropriations offers our partners with the government the certainty they need to invest in these important medical countermeasures which are a matter of national security. I urge the appropriators to fully fund the multiyear appropriations this legislation authorizes.

I'm proud that our legislation incorporates many provisions that were important to Members in both the Republican Conference, the Democratic Caucus, and to our colleagues in the Senate, to meet the needs of vulnerable communities during natural and manmade disasters.

The legislation also reauthorizes the HHS National Advisory Committee on Children and Disasters and authorizes the Children's Preparedness Unit at the CDC. This is critically important to address the persistent gaps in our nation's preparedness and response for the most vulnerable in many crises, our nation's children

The bill also establishes an Advisory Council for People with Disabilities and an Advisory Council on Seniors to focus on the needs of these special populations during a public health emergency.

It includes a proposal to prioritize bringing nursing homes back onto the power grid at the same time as hospitals after a disaster.

It includes provisions related to regional health partnerships, pregnant and postpartum women and environmental health.

I'm proud of this legislation and I urge my colleagues to support the Pandemic and All-Hazards Preparedness and Innovation Act.

Mrs. BROOKS of Indiana. Mr. Speaker, I include the following letters in the RECORD.

HEALTH INDUSTRY
DISTRIBUTORS ASSOCIATION,
July 17, 2018.

Hon. GREG WALDEN,
Chairman, House Energy and Commerce Committee, House of Representatives, Washington, DC.
Hon. SUSAN BROOKS,
House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy and Commerce Committee, House of Representatives, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives,
Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, CONGRESSWOMAN BROOKS AND CONGRESSWOMAN ESHOO: On behalf of the Health Industry Distributors Association (HIDA), we appreciate the opportunity to express our support for H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI). HIDA commends you for your leadership on this issue and appreciates the active engagement of your staff with industry to incorporate lessons learned from recent events such as Ebola and the 2017 hurricane season, in H.R. 6378, to continually improve our nation's preparedness capabilities.

HIDA is the trade association representing medical products distributors, all of which deliver medical products and supplies, manage logistics, and offer customer services to more than 294,000 points of care. HIDA members primarily distribute items used in every day medical services and procedures, ranging from gauze and gloves to diagnostic laboratory tests. Their customers include over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the country, as well as numerous federal agencies and their healthcare facilities.

As you know, the medical supply chain plays a critical role in preparedness, as it supplies key infection prevention products and protective equipment such as respirators, face shields, hoods, impermeable gowns and gloves to first responders and health care providers. Additionally, the medical supply chain is the primary source for the diagnostic and point-of-care rapid tests needed to identify infectious disease, as well as the ancillary products such as gloves, needles and syringes needed to deliver medical countermeasures effectively.

HIDA and its members have collaborated with federal agencies on identifying opportunities to improve coordination and develop solutions that create more elasticity in the supply chain for key products. One of the many lessons learned during the 2017 hurricane season was a considerable need to improve coordination during an emergency response, ensuring appropriate infrastructure partners are included in a prioritization process for access to affected areas after an event. We appreciate the Committees' acknowledgement of the importance of this issue in the legislation, as well as the recognition of the healthcare supply chain in H.R. 6378. Specifically, we support the following:

Section 101 provisions important to the healthcare supply chain including

The value of public and private sector coordination during an event to ensure critical supplies are delivered and information is shared.

The requirement that ancillary products needed to deliver a medical countermeasure are incorporated into the Public Health Emergency Medical Countermeasure Enterprise planning process.

Section 319C–3 provisions that create a regional healthcare system plan and that it be communicated to supply chain partners so needed product can be redirected during a response.

HIDA thanks you for your continued commitment to preparedness and look forward to working with you on H.R. 6378.

Sincerely,

LINDA ROUSE O'NEILL,
Vice President, Government Affairs,
Health Industry Distributors Association.

INFECTIOUS DISEASE SOCIETY OF AMERICA,
July 17, 2018.

Hon. GREG WALDEN,
Chairman, Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. FRANK PALLONE, Jr.,
Ranking Member, Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. SUSAN BROOKS,
Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. ANNA ESHOO,
Energy & Commerce Committee, House of Representatives, Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, REPRESENTATIVE BROOKS AND REPRESENTATIVE ESHOO: Thank you for your leadership in introducing H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI) that both reauthorizes and strengthens the Pandemic All-Hazards Preparedness Act (PAHPA). IDSA represents over 11,000 infectious diseases physicians and scientists. Many of our members work on the frontlines of public health emergencies, including bioterror attacks, outbreaks, and natural disasters (e.g., hurricanes that carry significant infectious diseases risks).

The programs and authorities contained within PAHPA provide essential resources for communities and health care facilities to prepare for and respond to public health threats. Further, PAHPA provides critical support for the research and development (R&D) of life-saving medical countermeasures (including vaccines, diagnostics, and antimicrobial drugs). In particular, IDSA is pleased to offer our strong support for the provision in H.R. 6378 to reinstate loan repayment authority for the Centers for Disease Control and Prevention to improve programs that train public health responders and future leaders, such as the Epidemic Intelligence Service. We also support the bill's attention to antimicrobial resistance. We look forward to working with the Committee on continued efforts to address this urgent public health threat.

A successful response to a public health emergency depends upon skilled personnel. Section 115 of H.R. 6378 will strengthen the ability of the CDC to recruit physicians to serve in the Epidemic Intelligence Service—a fellowship program that trains expert responders to infectious disease outbreaks and other public health emergencies. We greatly appreciate your inclusion of this important provision.

IDSA remains deeply concerned about antimicrobial resistance that threatens our national health security. We appreciate language in Section 302 authorizing the Biomedical Advanced Research and Development Authority to undertake strategic initiatives to address antimicrobial resistance, as well as Section 406 that codifies the Advisory Council on Combating Antibiotic Resistant Bacteria. These substantive efforts will continue to strengthen our national response to antimicrobial resistance, though we believe additional efforts will be essential to spur the research, development and appropriate use of urgently needed new antibiotics.

Once again, IDSA thanks you for your dedication to our nation's health security. We look forward to continuing to work with you on these crucial issues.

Sincerely,

PAUL G. AUWAERTER, MD, MBA, FIDSA,
President, IDSA.

NATIONAL ASSOCIATION OF COUNTY & CITY HEALTH OFFICIALS,
Washington, DC, July 18, 2018.

Hon. GREG WALDEN,
Chairman, House Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. SUSAN BROOKS,
U.S. House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives, Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, AND REPRESENTATIVES BROOKS AND ESHOO: On behalf of the National Association of County and City Health Officials (NACCHO), I am writing in support of the ''Pandemic and All-Hazards Preparedness Advancing Innovation Act (PAHPAIA) of 2018'' (H.R. 6378). NACCHO is the voice of the nearly 3,000 local health departments across the country that prepare communities for disasters, respond if emergencies occur, and lend support throughout the recovery process. PAHPAIA will provide needed stability for the nation's emergency preparedness and response enterprise. We thank you for your leadership on this legislation that is essential to protecting our nation and look forward to working with you to strengthen the legislation as it moves forward.

Among the many provisions in the bill, NACCHO highlights the following:

PHEP, HPP, MRC

The programs reauthorized in PAHPAIA are vital to local health departments. The Public Health Emergency Preparedness (PHEP) program and Hospital Preparedness Program (HPP), reauthorized in PAHPAIA, are complementary programs with different purposes. PHEP supports local health departments' response to public health threats and helps to build resilient communities. HPP enables health care systems to save lives during emergencies that exceed day-to-day capacity of health and emergency response systems. In addition, the Medical Reserve Corps (MRC) program provides additional public health personnel to respond to emergency needs as well as everyday health threats.

The PHEP, HPP and MRC programs deserve a level of funding that is consistent with the threats that are experienced on the ground level in cities and counties across the nation. In 2017, Congress spent a record breaking $80 billion to provide relief from Hurricanes Harvey, Irma and Maria, and devastating wildfires in California. Without the support of PHEP, HPP and MRC, the cost could have been much higher. A comprehensive, cost saving and proactive public health approach to disaster preparedness helps communities to effectively mitigate the damage and costs of disasters and help recover in the aftermath. Sustained funding to support local preparedness and response capacity helps local health departments build and convene diverse partners such as police, fire, transportation, planning departments, and community based organizations and develop and implement evidence-based, community-centered strategies.

MEDICAL COUNTERMEASURES

NACCHO supports the codification of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE Strategy and Implementation should require that state and local health departments be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures. NACCHO urges that state and local public health departments have a permanent place in the PHEMCE membership to ensure that all decisions that will affect state and local health functions are vetted by public health authorities.

Current funding, support, and expertise provided to state and local health departments for the Strategic National Stockpile must be maintained regardless of the infrastructure or location of the SNS—it is too vital to this country's ability to respond in the midst of a variety of large-scale emergencies.

PUBLIC HEALTH EMERGENCY FUND

NACCHO appreciates that the bill strengthens existing authorities for the Public Health Emergency Fund (PHEF). A standing rapid response fund to provide bridge funding between base preparedness funding and supplemental appropriations for acute emergencies and emerging threats is absolutely necessary.

NACCHO also appreciates the inclusion of provisions to maintain the pipeline of workers in the Epidemic Intelligence Service and to improve preparedness for children, seniors and people with disabilities. NACCHO appreciates the Committee's acknowledgement that pandemic influenza, antimicrobial resistance and other emerging infectious diseases are under the umbrella of the Biomedical Advanced Research and Development Authority's (BARDA) mission. Recent years have demonstrated that infectious diseases represent as significant a threat to our national security as a natural disaster or terror attack.

Thank you for your work to strengthen and enhance our nation's preparedness and response system. We look forward to continuing to work with you as this legislation moves forward.

Sincerely,

LORI TREMMEL FREEMAN, MBA,
Chief Executive Officer.

THE PARTNERSHIP FOR INCLUSIVE DISASTER STRATEGIES,
Charleston, SC, July 18, 2018.

Letter of Support for H.R. 6378—Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

DEAR REPRESENTATIVE ESHOO AND REPRESENTATIVE BROOKS: The Partnership for Inclusive Disaster Strategies (the Partnership) is the nation's only coalition of national, state and local stakeholder organizations working together to advocate for equal access to emergency and disaster services and programs for children and adults with disabilities before, during and after disasters. The footprint of our membership reaches every congressional district in the country, with a presence in virtually every community.

The Partnership drives disability community leadership, training, technical assistance, policy and operational initiatives that improve outcomes for disaster impacted communities through self-determination, health, safety, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of community preparedness, response and disaster resilience.

Our leaders include the nation's leading experts on disability inclusive emergency management. We have maintained a daily presence in support of disaster response, recovery and mitigation initiatives in TX, FL. USVI and PR since hurricanes Harvey, Irma and Maria made landfall in 2017, and our current focus includes the impact on individuals

with disabilities and disaster impacted communities from the wild fires in CA and the lava flows in Hawaii.

Despite thousands of disaster related deaths and the disproportionate impact of the disasters on countless people with ''chronic health conditions'' (also clearly defined as disabilities under the ADA legal definition) in 2017 & 2018, the recently released FEMA After Action Report only mentions disability in a footnote and a list of acronyms defining the position of Disability Integration Advisors, never in any other context.

Further, according to FEMA, ''the hurricanes and wildfires collectively affected more than 47 million people—nearly 15 percent of the Nation's population''. Given these statistics, it is likely that close to 10 million of these disaster impacted individuals should have been provided with the civil rights protections of equal access to emergency services and programs. It is unfortunate that there is no indication of any focus in the document on FEMA's obligations, efforts or recommendations.

Clearly there is an urgent need for advice and consultation from disability inclusive emergency management experts to improve outcomes for disaster impacted children and adults with disabilities and their communities.

We are writing in support of H.R. 6378-Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, with specific support for Section 110, the establishment of a NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES IN ALL-HAZARDS EMERGENCIES.

The Advisory Committee will:

1. provide advice and consultation with respect to activities carried out pursuant to section 2814, as applicable and appropriate;

2. evaluate and provide input with respect to the public health, accessibility, and medical needs of individuals with disabilities as they relate to preparation for, response to, and recovery from all-hazards emergencies; and

3. provide advice and consultation with respect to State emergency preparedness and response activities, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

We are especially interested in the Committee report which will include recommendations that offer specific improvements that could be made across local, State, tribal, territorial, and Federal efforts to improve outcomes in areas that include—

''(A) preparedness;

''(B) planning;

''(C) exercises and drills;

''(D) alerts, warning, and notifications;

''(E) evacuation;

''(F) sheltering;

''(G) health maintenance;

''(H) accessing emergency programs and services;

''(I) medical care (including mental health care);

''(J) temporary housing;

''(K) mitigation; and

''(L) community resilience; and

''(2) assess the strength of existing policies to incorporate such individuals as well as the efficacy of implementation.

We offer our enthusiastic support for the membership of this Committee, which will include

at least four representatives who are individuals with disabilities that have substantive expertise in disability inclusive emergency management policy and operations;

at least two non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery; and

at least two representatives from State, local, territorial, or tribal agencies with expertise in disability-inclusive disaster planning, preparedness, response, or recovery.

The Partnership applauds your leadership and welcomes every opportunity to work with you, and your colleagues to ensure that establishment of this vital Advisory Committee is included in final passage of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

Sincerely,

MARCIE ROTH,
Chief Executive Officer.

PEW CHARITABLE TRUSTS,
Washington, DC, July 17, 2018.

Hon. GREG WALDEN,
Chairman, House Energy and Commerce Committee, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy and Commerce Committee, Washington, DC.
Hon. SUSAN W. BROOKS,
House Energy and Commerce Committee, Washington, DC.
Hon. ANNA G. ESHOO,
House Energy and Commerce Committee, Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, CONGRESSWOMAN BROOKS AND CONGRESSWOMAN ESHOO: The Pew Charitable Trusts thanks you for your continued efforts to respond to the ongoing threat of antibiotic resistance through the introduction of H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPA). This important legislation reauthorizes the essential work of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)'s Biomedical Advanced Research and Development Authority (BARDA) to address public health emergencies and bring desperately-needed antibiotics to patients. Effective antibacterials are central to the nation's ability to respond to public health threats, including chemical, biological, radiological, and nuclear attacks (CBRN), pandemic influenza, and emerging infectious disease—antibiotics are an integral part of the nation's armament to address these threats.

We especially want to thank the Members of the House Energy and Commerce Committee for including language related to antibiotic resistance in Section 302 of PAHPA. This language will ensure that BARDA is explicitly authorized to address all CBRN threats—both intentional and naturally occurring—through robust support of innovative approaches in both preclinical and clinical development. BARDA's unique experience working with industry to drive innovation is particularly important to advance novel therapeutics and preventive interventions and to help bridge the gap between basic science and successful clinical drug development.

BARDA safeguards our nation's health infrastructure by revitalizing and encouraging antibacterial innovation to ensure that we have a healthy pool of candidate products to address emerging threats. The CARB–X accelerator addresses critical gaps along the early stages of the antibacterial pipeline, and BARDA's Broad Spectrum Antimicrobials program advances therapeutics into late stage clinical development. The two programs work in tandem to support a robust pipeline of novel approaches for highly resistant infections and emerging threat pathogens.

Thank you for continued support of this important work.

Sincerely,

KATHY TALKINGTON,
Antibiotic Resistance Project Director.

AMERICAN ASSOCIATION OF POISON CONTROL CENTERS,
Alexandria, VA, July 20, 2018.

Hon. SUSAN BROOKS,
Washington, DC.
Hon. ANNA ESHOO,
Washington, DC.

DEAR CONGRESSWOMEN BROOKS AND ESHOO: The American Association of Poison Control Centers (AAPCC) would like to extend our support for H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

As you already know, AAPCC supports the nation's 55 poison control centers in their efforts to prevent and treat poison exposures. Poison control centers across the U.S. receive approximately 3 million calls annually that cover a variety of substances, including prescription and over-the-counter medications, illegal drugs, household products, pesticides, cosmetics, environmental toxins, food, plants, and animal bites and stings. These calls come from a wide variety of individuals, including the public, health care providers, 911 PSAPs (Public Safety Answering Points), schools, health departments, law enforcement, and other safety agencies. The centers operate 24 hours a day, 7 days a week, 365 days a year and are accessed through a federally funded nationwide toll free number: 800–222–1222 (Poison Help).

When someone calls 800–222–1222, the calls are answered by highly trained Specialists in Poison Information (pharmacists and nurses), who diagnose, triage, and offer treatment recommendations to callers with 24-hour oversight from Board Certified Medical and Clinical Toxicologists. We answer calls from every state and territory in our nation. We know that you and your staff are already familiar with the wonderful work of the Indiana Poison Center and the California Poison Control System.

There are three references, all in Title II, to poison centers in Public Law 113–5 (the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013). These provisions allow states and public health departments to work directly with their regional poison center and have resulted in improved preparedness preparations in multiple communities throughout the nation. Thank you for keeping these poison center references in H.R. 6378.

We also deeply appreciate your inclusion of poison centers in Section 207, Regional Health Care Emergency Preparedness and Response Systems. Poison centers have a unique set of knowledge and are the primary source for poisoning information. Our employees are trained to handle stressful, potentially life altering situations on a daily basis and we already have the infrastructure in place as a 24/7 365 days a year call center. We are a vital resource on a number of topics from chemical spills to mass exposure to an unknown toxin to a public health emergency including the pandemic flu or Ebola and Zika. The poison control system is a well-established, nationwide network made up of sophisticated and specially trained medical professionals who handle calls related to over 420,000 products and substances and their related toxicities.

Our poison centers support your efforts and look forward to our work together on this important topic. Finally, a special thank you to your staff, Catherine Knowles and Rachel Fybel for all of their assistance. Thank you, as always, for your continued support of our 55 poison centers.

Warmest regards,

WILLIAM BANNER, Jr., MD, PhD,
President, AAPCC, Oklahoma Center for Poison & Drug Information.

STEPHEN KAMINSKI, JD,
CEO and Executive Director, AAPCC.

Mrs. BROOKS of Indiana. Mr. Speaker, I include the following letters in the RECORD.

AMERICAN SOCIETY
FOR MICROBIOLOGY,
Washington, DC, July 23, 2018.

Hon. PAUL RYAN,
Speaker of the House, House of Representatives, Washington, DC.
Hon. GREG WALDEN,
Chairman, Energy and Commerce Committee, House of Representatives, Washington, DC.
Hon. SUSAN BROOKS,
House of Representatives, Washington, DC.
Hon. NANCY PELOSI,
Minority Leader, House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, Energy and Commerce Committee, House of Representatives, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives,
Washington, DC.

DEAR SPEAKER RYAN, MINORITY LEADER PELOSI, CHAIRMAN WALDEN, RANKING MEMBER PALLONE, REPRESENTATIVE BROOKS AND REPRESENTATIVE ESHOO: The American Society for Microbiology (ASM) congratulates the Energy and Commerce Committee on its passage of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (H.R. 6378) and encourages its swift passage in the House.

ASM is the largest single life science society, composed of more than 32,000 scientists and health professionals. Our mission is to promote and advance the microbial sciences, including programs and initiatives funded by the federal government departments and agencies, by virtue of the pervasive role of microorganisms in health and society.

Antimicrobial resistance is among the most consequential issues facing world today. ASM is therefore pleased that H.R. 6378 includes Section 406, a provision that would guarantee the continued work of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) by codifying the Advisory Council. A guarantee of PACCARB's continuance also sustains the One Health partnerships—the integration of human, animal, and environmental domains—that have been formed since the establishment of PACCARB.

This year marks the 100th anniversary of the Influenza Pandemic of 1918, which killed almost 40 million people, and serves a reminder that the United States must be prepared to rapidly respond to declared and potential public health emergencies, including infectious disease epidemics.

ASM strongly supports the legislation's reauthorization of the Biomedical Advanced Research Development Authority (BARDA) and is pleased to see inclusion and authorization of a Pandemic Influenza Program and Emerging Infectious Disease Program. Authorization of funding for the Strategic National Stockpile and the Bioshield Special Reserve Fund are all critically important to our public health security. Therefore, it is important that reauthorization be met with a corresponding commitment of federal resources.

Lastly, ASM appreciates that the legislation points to the need for an adequately funded Public Health Emergency Fund (PHEF) and strengthens existing authorities for which PHEF dollars may be used, including in anticipation of a potential public health emergency. Vigilance will be required to make sure our country is adequately prepared to make financial resources available in a timely manner to potential or immediate public health emergencies, and so we look forward to your continued leadership in this regard.

ASM believes that H.R. 6378 will further our nation's preparedness to respond in a timely and coordinated manner to declared and potential public health threats. Toward this end, ASM strongly supports swift final passage by the Senate and House. We appreciate your championship of these issues and stands ready to work with you towards this goal. Should you have any questions, please contact Allen Segal, Director, ASM Public Policy and Advocacy.

Sincerely,

STEFANO BERTUZZI, PH.D., MPH,
CEO, American Society for Microbiology.
ALLEN D. SEGAL,
Director, Public Policy and Advocacy, American Society for Microbiology.

ASTHO, SEPTEMBER 23, 2018.

Hon. LAMAR ALEXANDER,
Chairman, Health, Education, Labor and Pensions Committee, U.S. Senate, Washington, DC.
Hon. GREGG WALDEN,
Chairman, Energy & Commerce Committee, House of Representatives, Washington, DC.
Hon. PATTY MURRAY,
Ranking Member, Health, Education, Labor and Pensions Committee, U.S. Senate, Washington, DC.
Hon. FRANK PALLONE, Jr,
Ranking Member, Energy & Commerce Committee, House of Representatives, Washington, DC.

DEAR CHAIRMAN ALEXANDER, RANKING MEMBER MURRAY, CHAIRMAN WALDEN, AND RANKING MEMBER PALLONE: The Association of State and Territorial Health Officials (ASTHO) submits this letter in support of most of the public health provisions included in the ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018'' (H.R. 6378). ASTHO is the national nonprofit organization representing the state and territorial public health agencies of the United States, U.S. territories, and Washington, D.C. ASTHO's members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and assuring excellence in public health practice.

ASTHO is pleased that this bill retains elements proven to be necessary, reasonable, and successful, while making further refinements to the underlying statute, as well as responding to and including many of ASTHO's priorities. These priorities, outlined in previously submitted comment letters, include suggestions for clarifications and acknowledgments regarding the importance of state, local, territorial, and tribal public health. These provisions include:

Reauthorizing the Public Health Emergency Preparedness Program (PHEP) and Hospital Preparedness Program (HPP). PHEP and HPP are key to the foundational capabilities of public health preparedness and healthcare

Codifying the role of CDC to administer the PHEP program

Bolstering the Public Health Emergency Rapid Response Fund and mechanisms to quickly distribute funds

Requiring that the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) solicit and consider input from state, local, tribal, and territorial public health departments or officials

Improving the nation's ability to take a ''OneHealth'' approach to preparedness and response capabilities

Reauthorizing the temporary reassignment of state and local personnel during public health emergencies

Requiring the HHS secretary, in collaboration with ASPR and CDC, to maintain the strategic national stockpile

Including a provision to strengthen the Epidemic Intelligence Service by increasing the loan repayment amount from $35,000 to $50,000

In addition, ASTHO expresses our concern and seeks clarification from the committee on changes to HPP, particularly those that alter eligibility requirements for funding from a ''partnership'' to''coalitions.'' One of the most crucial functions of HPP is to bring together and incentivize ''diverse and often competitive healthcare organizations to work together.'' As neutral conveners, state and territorial public health departments are the most appropriate entities and stewards of taxpayer dollars. They are also responsible for statewide planning and coordination of services and fundamentally serve all residents in their jurisdictions—not just lives covered under a plan or specific catchment area. With the establishment of hundreds of Healthcare Coalitions across the country, ASTHO seeks assurance that the letter, spirit, and intent of this modification does not in any way change the current cooperative agreement structure and stature, nor does it alter the role and responsibilities of states, territories, and directly-funded cities as awardees of funds under HPP.

ASTHO also remains concerned that authorization levels—$685 million for PHEP and $385 million for HPP—are significantly lower than our suggested authorization levels of $824 million for PHEP and $474 million for HPP. ASTHO is concerned that authorizing at these proposed levels will be insufficient. Both PHEP and HPP must be resourced at sufficient levels to ensure that every community is prepared for disasters. An efficient and effective state and local workforce depends heavily on reliable, ongoing funding support for a network of state and local expertise, relationships and trust that is carefully built over time through shared responses, training, and exercises.

Regarding sections that speak to ''reservations of amounts for regional systems,'' ASTHO would also like to reiterate that HPP is already funded at a vastly insufficient level given the task of preparing the healthcare system for a surge of patients, continuity of operations, and recovery. Any funding reductions to HPP through a tap will have an adverse impact on real-time all-hazards preparedness and response activities carried out by the existing healthcare coalitions. The costs associated with exploring the development of a regional system or network should not be at the expense of current critical medical readiness and patient care services.

Finally, while we appreciate that the bill strengthens existing authorities for the Public Health Emergency Fund, we continue to urge Congress to create a mechanism to fund and replenish it. Without sufficient and dedicated funding, it will be impossible to quickly access funds when needed.

ASTHO appreciates the opportunity to provide our comments on this critical legislation and the bipartisan efforts of both the House and Senate committees.

Sincerely,

JOHN WIESMAN, DRPH, MPH,
ASTHO President, Secretary of Health, Washington State Department of Health Olympia, WA.

BIOTECHNOLOGY INNOVATION ORGANIZATION,
September 24, 2018.

Hon. SUSAN BROOKS,
House of Representatives, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives, Washington, DC.

DEAR REPRESENTATIVES BROOKS AND ESHOO: On behalf of the Biotechnology Innovation Organization (BIO), I am writing to express our strong support for final passage of H.R. 6378, the ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''. I wish to commend you for your extraordinary work getting this legislation to the House floor.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members are committed to investing in, developing, and delivering innovative vaccines, therapeutics, and diagnostic tools that are transforming how we protect, treat and cure people from devastating infectious diseases. Many of BIO's members are active partners with the U.S. government to strengthen our national health security through the development and stockpile of medical countermeasures (MCM) against the myriad threats facing our nation. The value that these MCMs offer to first responders, patients and their caregivers, and the global community is phenomenal.

BIO was pleased to see the Act continue to provide support for critical preparedness programs such as the BioShield Special Reserve Fund (SRF), the Biomedical Advanced Research and Development Authority (BARDA), and the Strategic National Stockpile (SNS)—all of which are necessary to ensure that we can maintain a robust medical countermeasures enterprise that can address known and unknown threats. We are also pleased to see that significant threats such pandemic influenza, emerging infectious diseases, and antimicrobial resistance are specifically recognized in the Act and that BARDA has been authorized appropriations to address these dangerous threats. We are very supportive of the overall authorization of $2.4 billion annually to the MCM enterprise, which will allow the Secretary of Health and Human Services to more fully prepare for many of the threats affecting our national health security.

BIO thanks you for your commitment to our national health security and your important work to ensure that our nation is adequately prepared to respond to the myriad threats we face domestically and abroad. BIO and our member companies look forward to continuing to work with you to further strengthen our preparedness against all potential national security and public health threats as outlined in the National Biodefense Strategy.

With Sincerest Regards,
JAMES C. GREENWOOD,
President and CEO.

CALIFORNIA LIFE SCIENCES ASSOCIATION,
July 16, 2018.

Hon. SUSAN BROOKS,
Washington, DC.
Hon. ANNA G. ESHOO,
Washington, DC.

DEAR REPRESENTATIVES BROOKS AND ESHOO: On behalf of California Life Sciences Association (CLSA)—the statewide public policy organization representing California's leading life science innovators, including medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms—I am writing to express our support for H.R. 6378, the Pandemic and All Hazards Preparedness and Advancing Innovation (PAHPAI) Act of 2018, your legislation that will strengthen and improve our national preparedness and response for public health emergencies, and accelerate medical countermeasure research and development. Thank you for your leadership on this critically important issue.

As you know, the recent Ebola and Zika outbreaks and ongoing threats from terrorist organizations like ISIS have repeatedly exposed our nation's continued vulnerability to bioterror and pandemic threats, demonstrating the need for robust biodefense preparedness. Robust, long-term funding, and strong and sustained public-private partnerships remain critical in ensuring a well-funded, well-coordinated, swift and effective response from all stakeholders. This includes, critically, a robust statutory framework for securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI), antimicrobial resistance (AMR), and emerging infectious diseases (EID).

To that end, H.R. 6378 strengthens our country's national preparedness and response efforts for public health emergencies by codifying the Public Health Emergency Medical Countermeasure Enterprise and the duties of the Assistant Secretary for Preparedness and Response (ASPR), while maintaining the important role of the Centers for Disease Control in emergency and response activities. The legislation also provides the authorization and federal resources to invest in programs related to Pandemic Influenza and Emerging Infectious Diseases.

We are pleased the bill provides new authorities to the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives for threats that pose a significant level of risk to national security, including antimicrobial resistant pathogens. We also encourage you to continue working with you colleagues on the House Committee on Energy & Commerce and congressional leadership to explore the creation of new incentives to encourage investment into the development of products to treat or prevent a disease attributable to a multi-drug resistant bacterial or fungal pathogen.

According to the Centers for Disease Control and Prevention (CDC), each year at least two million people in the United States are infected with bacteria that cannot be treated with an antibiotic, resulting in roughly 23,000 deaths and health care costs as much as $20 billion annually. These staggering statistics illustrate a dangerous reality: even as the rate of anti-microbial resistance has grown, research and drug development has not kept pace with the dire need for new medicines to treat these increasingly lethal ''superbugs.''

Given the threat that these deadly pathogens pose to public health in the United States and across the world, the need for effective public-private partnerships between the government, academia and industry has never been greater. The growing epidemic of multidrug-resistant infections knows no borders and the reestablishment of antibiotic development as a viable investment for life sciences innovators is imperative to public health and preparedness.

Thank you again for your leadership of H.R. 6378, as well as your long-standing support for legislation and policy measures that improve our nation's biodefense preparedness and response capabilities.

CLSA is pleased to join a broad group of stakeholders in offering our strong support for H.R. 6378, the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2018. Please let me know if CLSA can be of assistance to you.

Sincerely,
JENNIFER NIETO CAREY,
Vice President—Federal Government Relations & Alliance Development.

CELLPHIRE,
Rockville, MD, July 18, 2018.

Hon. GREG WALDEN,
Chairman, House Energy and Commerce Committee, Washington, DC.
Hon. SUSAN BROOKS,
House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy and Commerce Committee, Washington, DC.
Hon. ANNA ESHOO,
House of Representatives, Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE AND REPRESENTATIVES BROOKS AND ESHOO: We write in support of HR 6378, the Pandemic and All Hazards Preparedness Act (PAHPA) Reauthorization. Cellphire supports the Committee's inclusion of the national blood supply in the Committee markup of PAHPA. Numerous inquiries and hearings conducted after 9/11 revealed the need for a coordinated response to insure preparedness through maintaining an adequate blood supply and providing a rapid coordinated response system to distribute blood products immediately to the affected area(s) as well as recruit and manage donations required for continual resupply during the crisis. The need for a coordinated response to the nation's blood needs was first recognized in the National Response Plan, Emergency Support Function #8, Public Health and Medical Services Annex:

Blood, Organs, and Blood Tissues—ESF #8 may task HHS components and request assistance from other ESF #8 partner organizations to monitor and ensure the safety, availability, and logistical requirements of blood, organs, and tissues. This includes the ability of the existing supply chain resources to meet the manufacturing, testing, storage, and distribution of these products.

We applaud the Committee's recognition of the national blood supply's importance as referenced in Section 116 which requires the Secretary of Health and Human Services to provide a report on recommendations related to maintaining an adequate blood supply Hospitals across the nation as well as blood product companies like Cellphire are dependent on the stability of the blood supply and the ability of the U.S. blood supply ''system'' to respond to disaster. The organizations representing the nation's blood centers, hospital-based blood banks and transfusion services, and transfusion medicine professionals have requested that you consider asking the Office of the Assistant Secretary for Preparedness and Response (ASPR) to make the sustainability of our nation's blood supply a critical element of our emergency preparedness and response systems. In addition, a joint letter to the New England Journal of Medicine authored by Harvey Klein MD, Chief Department of Medicine, the NIH Clinical Center, Chris Hrouda, President ARC Biomedical Services, and Jay Epstein MD, Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA, warned of an approaching crisis in the sustainability of the U.S. Blood System. The concern regarding the sustainability and responsiveness of the U.S. blood supply was also raised by a RAND Corporation study initiated by the Department of Health and Human Services, ''Toward a Sustainable Blood Supply in the United States, An Analysis of the Current System and Alternatives to the Future''.

The goal at Cellphire, currently supported by the ASPR through BARDA, is to develop and field a freeze-dried platelet product to stop hemorrhage that can alleviate platelet shortages and lead to a life-saving product that controls bleeding and can be stockpiled. Supplying, distributing and resupplying this and other blood products during a crisis requires a sustainable blood supply.

The PAHPA Re-authorization bill includes language for the Assistant Secretary of Preparedness Response (ASPR) to include the stability of the blood supply as it considers guidelines for infrastructure. Section 203 further lists the blood banks in the stakeholder groups with whom ASPR should engage to obtain feedback on financial implications as it relates to regional preparedness planning pursuant to the guidelines.

We believe the reference to the national blood supply and the inclusion of the blood collection centers and hospital blood banks in ASPR guidelines to establish infrastructure and regional preparedness planning will ensure our nation's blood supply is ready and prepared for surge capacity in the event of a disaster or terrorist attack.

Thank you for your leadership in addressing the blood supply in HR 6378, the PAHPA Reauthorization. We support the Committee's attention to this urgent matter of national security.

Sincerely,

MICHAEL FITZPATRICK,
Ph.D , COL (Ret.) U.S. Army,
President and Director of Research, Cellphire, Inc.

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS,
July 17, 2018.

Hon. GREG WALDEN,
Chairman,
Washington DC.
Hon. FRANK PALLONE,
Ranking, Energy and Commerce Committee, Washington DC.

DEAR CHAIRMAN WALDEN AND RANKING MEMBER PALLONE: I write in strong support of HR 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPA.) As you know, public health emergencies can result from natural disasters, emerging pathogens, or man-made threats. Just last year we saw health challenges emerge on multiple fronts due to hurricanes, a virulent strain of the flu, and outbreaks of plague, Lassa, Nipah and Ebola overseas. The United States must do everything in its power to prepare for health emergencies, and HR 6378 goes a long way towards helping the Department of Health and Human Services (HHS) achieve that goal.

As the CEO of CEPI, an international coalition whose mission it is to develop vaccines to prevent future epidemics, I am heartened to see language in the bill asking HHS to report on its work developing vaccines to prevent epidemics, including its collaborations with international organizations (Section 303). As we saw in the recent Ebola outbreak in the Democratic Republic of Congo, vaccines and international coalitions can play a critically important role in outbreak response and HHS should maximize its support for this kind of vaccine research and development.

I am also pleased that HR 6378 creates an emerging infectious disease program within the Biomedical Advanced Research and Development Authority (BARDA) [Section 302]. CEPI would welcome the opportunity to partner with BARDA on future vaccine candidates for emerging infectious diseases of global significance. In addition, the codification of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is another important feature of this bill [Section 101]. The PHEMCE works to ensure that medical countermeasure development is aligned across the government and that bottlenecks can be anticipated and prevented, which is important to prevent costly duplication of work and other inefficiencies.

In summary, I believe that HR 6378 will strengthen US public health preparedness, particularly when it comes to vaccines and medical countermeasure development and coordination, and I am pleased that it will be considered by your committee.

Sincerely,

RICHARD HATCHETT, CEO.

Mrs. BROOKS of Indiana. Mr. Speaker, I include the following letters in the RECORD.

CERUS,
Concord, CA, July 17, 2018.

Hon. GREG WALDEN,
Chairman, House Energy and Commerce Committee, House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, House Energy & Commerce Committee, House of Representatives, Washington, DC,

DEAR CHAIRMAN WALDEN AND RANKING MEMBER PALLONE: As you review and deliberate over H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, we wanted to provide our support for the efforts in the legislation to preserve and protect the nation's blood supply—especially in a public health emergency.

As you know, the American public expects the nation's blood supply is safe and available every day, but especially in situations of natural or man-made disasters. Blood transfusions can be lifesaving measures, but this depends on our collective ability to ensure the safety and availability of the blood supply. Though the danger of transfusion-transmitted infections has decreased in recent years due to improved blood testing for specific pathogens such as HIV and hepatitis, these tests do not detect the presence of all viruses, bacteria, and parasites known to contaminate blood donations. In 2015 at the height of the Zika epidemic in Puerto Rico, the FDA released guidance calling for the use of blood treatment pathogen reduction technology as an option to reduce the risk of transfusion-transmission of Zika. This pathogen reduction technology helped ensure that very ill patients would have adequate access to safe blood and that they would not contract Zika virus infection from their therapeutic blood transfusions.

Section 116 is critical to ensuring the blood collection community, in concert with the Department of Health and Human Services, begins to cohesively examine the challenges with preserving capacity in the nation's blood supply for major emergency care, addressing issues like recruiting sufficient donors to ensure the adequacy of the current supply to meet public health emergencies and implementation of innovative and best safety practices.

The inclusion of blood banks in Section 203 is also critical for ensuring the blood banking community has an opportunity to engage along with hospitals, health care facilities, public agencies and others to provide input into our nation's new ''Healthcare Preparedness and it Response Program.'' The inclusion of blood banks is critical in providing feedback on the financial implications for the program as the industry faces many challenges in ensuring a transfusion-ready blood supply.

I sincerely appreciate the time and effort that both of you, your fellow Committee members and the staff have placed in drafting, reviewing, and deliberation over H.R. 6378. I look forward to continuing to work with all of you in supporting our nation's ability to respond in public health emergencies.

Sincerely,

DR. LAURENCE CORASH, MD
Chief Scientific Officer, Cerus.

JULY 19, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce, Washington, DC.
Hon. SUSAN W. BROOKS,
Washington, DC.
Hon. FRANK PALLONE, Jr.,
Ranking Member, Committee on Energy and Commerce, Washington, DC.
Hon. ANNA ESHOO,
Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, AND REPRESENTATIVES BROOKS AND ESHOO: Child Care Aware of America cares deeply about the health and well-being of children and their success in child care. We would like to thank you for your bipartisan commitment to reauthorizing the Pandemic and All-Hazards Preparedness Act. As the Pandemic and All-Hazards Preparedness (PAHPA) and Advancing Innovation Act of 2018 moves forward, we want to voice our support for extending and expanding the authorization of the National Advisory Committee on Children and Disasters (NACCD) to address the ongoing gaps in our nation's preparedness and response for children. Recent natural disasters such as Hurricanes Harvey, Irma and Maria have demonstrated that our nation still is not fully prepared to respond to the child care needs of children.

We also appreciate the proposed additional expertise to the NACCD to include non-federal experts in pediatric mental or behavioral health, pediatric infectious disease, children's hospitals, and children and youth with special health care needs, and particularly, professionals with expertise in child care or school settings.

The NACCD was established to provide advice and consultation to the Department of Health and Human Services (HHS) Secretary and the Assistant Secretary for Preparedness and Response (ASPR) on issues related to the medical and public health needs of children before, during, and after disasters. The NACCD has completed several reports in recent years focused on youth leadership, surge capacity, and the provision of human services. Their expertise has been invaluable in ensuring that children are protected during public health emergencies and disasters.

Our organization learned that after Hurricane Irma, 22% of the child care facilities in the state of Florida were closed due to the storm. In the Miami-Dade-Monroe area specifically, 32% of facilities were closed. Following Hurricane Harvey, 18% of child care facilities were closed in the Houston area. This means that thousands of children and their families were left without child care. This carries an incredible burden on families as they struggle to find child care when they are needed at work. Furthermore, the interruption of normalcy can cause stress on children leading to negative consequences for brain development. Including expertise in child care will help in making sure that the needs of the 11 million children in child care will be met before, during, and after a disaster.

Children are not little adults. They have specialized needs that must be considered when planning for, responding to, and recovering from a disaster. This includes having a strong, well-funded public health and medical system. We thank you considering the many needs of children and including them

in the Pandemic and All-Hazards Preparedness (PAHPA) and Advancing Innovation Act of 2018.

Sincerely,

CHILD CARE AWARE OF AMERICA.

CHIME & AEHIS,
July 23, 2018.

Re Inclusion of Cybersecurity in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

Hon. GREG WALDEN,
Chairman, House Committee on Energy and Commerce, House of Representatives, Washington, DC.

Hon. FRANK PALLONE,
Ranking Member, House Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR CHAIRMAN WALDEN AND RANKING MEMBER PALLONE: The College of Healthcare Information Management Executives (CHIME) and the Association for Executives in Healthcare Information Security (AEHIS) sincerely appreciate the inclusion of cybersecurity provisions in section 401 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. This critical section of legislation recognizes the importance of ensuring the nation's health systems are better prepared and better able to respond in the event of a cybersecurity incident.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. Consisting of more than 2,600 members in 51 countries, our members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation. CHIME members are among the nation's foremost health IT experts, including on the topic of cybersecurity. Launched by CHIME in 2014, AEHIS represents more than 850 chief information security officers (CISOs) and provides education and networking for senior IT security leaders in healthcare. CHIME and AEHIS members take their responsibility to protect the privacy and security of patient data and devices networked to their system very seriously.

The widespread attacks experienced by health systems worldwide during the spring of 2017 highlighted the need to consider the cybersecurity readiness of the healthcare sector and demonstrated the importance of increased preparedness and rapid response in the event of an incident. Cybersecurity threats are growing in frequency and sophistication coming from a variety of actors seeking to send our country's healthcare system into disarray. Our members continue to worry about the threats to patient care and safety posed by cybersecurity attacks.

CHIME and AEHIS appreciate the inclusion of cybersecurity in the Pandemic All Hazards Preparedness Reauthorization Act of 2018. We agree that cybersecurity threats and the recognition of their potential to disrupt healthcare delivery is of the utmost importance to patient safety and therefore, needs to be a part of the National Health Security Strategy. CHIME and AEHIS believe it is imperative that cybersecurity is treated as a threat to our nation in similarity to other hazards. We also appreciate the designation of the Assistant Secretary for Preparedness and Response (ASPR) as the leader within the Department of Health and Human Services (HHS) in the event of a cybersecurity incident. Our members have repeatedly cited confusion, leading to frustration, about which operating division within HHS has responsibility over cybersecurity and serves as a liaison to the industry.

We appreciate your continued interest and leadership on this important and increasingly urgent subject. We stand ready to work with you and your colleagues to pursue legislative solutions to improve the cybersecurity readiness of the nation's healthcare sector.

Sincerely,

CLETIS EARLE,
Chair, CHIME Board of Trustees Vice President, CIO Information Technology, Kaleida Health.

ERIK DECKER,
Chair, AEHIS Board CISO and Chief Privacy Officer, University of Chicago Medicine.

EMERGENT BIOSOLUTIONS,
July 17, 2018.

Hon. SUSAN BROOKS,
Washington, DC.

Hon. GREG WALDEN,
Washington, DC.

Hon. ANNA ESHOO,
Washington, DC.

Hon. FRANK PALLONE,
Washington, DC.

DEAR REPS. BROOKS, ESHOO, WALDEN, AND PALLONE: Thank you to you and your staff for your hard work in introducing H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. This legislation, like PAHPRA and PAHPA before it, is vital to ensuring our nation is safe from and prepared for both human-deployed and natural chemical, biological, radiological, and nuclear (CBRN) threats. Emergent is pleased to support PAHPAI.

We are appreciative of your staff for taking the time to meet with us and solicit feedback about the PAHPAI. Thank you for your leadership in ensuring the legislation further strengthens our nation's preparedness for biological threats.

Funding Levels: Emergent strongly supports the robust funding levels authorized in PAHPAI. This funding is needed to continue to grow the public-private partnership Congress created to ensure the U.S. is adequately prepared for CBRN threats. Sustained and expanded investment in these programs is a vital market pull to ensure private partners produce medical countermeasures for the most serious threats we face as a nation, such as anthrax, smallpox, and chemical threats. If the government fails to adequately support the Special Reserve Fund, BARDA, and the SNS, the nation faces the dual risk of squandering resources already invested into research and preparedness, while also being underprepared or unprepared for material threats to our national security.

Identified Authorization Funding Levels for Key Programs: Emergent is strongly supportive of the inclusion of specific funding authorization that breaks out the minimum amounts for the critical Pandemic Influenza and Emerging Infectious Disease (EID) activities supported through BARDA. Specific authorizations help ensure that BARDA's priorities receive consistent funding needed to drive the development of countermeasures to respond to material threats, pandemic influenza, emerging infectious diseases, and other public health hazards.

Other Transaction (OT) Authority: We appreciate your efforts to update the medical countermeasure enterprise's OT authority and harmonize it with the OT authority of other agencies. These changes will provide the enterprise needed flexibility to better prepare for manmade and naturally-occurring biological threats.

The public health threat matrix is real and growing. Reauthorization of PAHPAI is vital to ensuring our nation is prepared for the most severe threats facing the country. As introduced, PAHPAI will greatly enhance our nation's biosecurity preparedness. We believe that Emergent is uniquely positioned to enable the U.S. and allied governments to address many of these threats based on our growing portfolio of medical countermeasures, decades of experience and expertise in government partnering and contracting, and our broad and deep manufacturing capabilities. We hope we can be a resource as the committee continues to work towards passage of PAHPAI.

Sincerely,

CHRIS FRECH,
Senior Vice President, Global Government Affairs, Emergent BioSolutions, Inc.

GENENTECH,
Washington, DC, 17 July 2018.

Hon. ANNA G. ESHOO,
House of Representatives, Washington, DC.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

Hon. SUSAN W. BROOKS,
House of Representatives, Washington, DC.

Hon. FRANK PALLONE, Jr.,
Ranking Member, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR REPRESENTATIVES ESHOO AND BROOKS, CHAIRMAN WALDEN, AND RANKING MEMBER PALLONE: Genentech, Inc. (Genentech) would like to express our strong support for H.R. 6378—The Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2018. We applaud your shared leadership and bipartisan efforts to strengthen the nation's public health preparedness and response programs. We are particularly appreciative that H.R. 6378 authorizes a specific Pandemic Influenza program at the Biomedical Advanced Research and Development Authority (BARDA) to support research and development activities to enhance a rapid response to pandemic influenza.

As you continue your work toward reauthorization, Genentech welcomes the opportunity to share our relevant experience and provide any needed feedback.

Sincerely,

DAVID BURT,
Senior Director, Federal Government Affairs.

GRIFOLS PUBLIC AFFAIRS,
Washington, DC, July 24, 2018.

Hon. SUSAN BROOKS,
House of Representatives, Washington, DC.

Hon. ANNA ESHOO,
House of Representatives, Washington, DC.

DEAR CONGRESSWOMAN BROOKS AND CONGRESSWOMAN ESHOO: Thank you for your leadership on healthcare issues in the Congress. Grifols is proud to join the public health and infectious disease communities in expressing our strong support for H.R. 6378, the ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.'' This legislation is critical to maintaining our national preparedness in response to public health emergencies.

Grifols is a global healthcare company with a 75-year history of producing plasma-derived medicines, diagnostic tools and hospital pharmacy products. Grifols is a leader in transfusion medicine as a supplier of blood and plasma infectious disease screening systems that are critical to safeguarding the U.S. blood supply.

The Nation's experience with emerging infectious diseases, such as Zika, demonstrates the need for a coordinated response to public health threats. In a report commissioned by the Department of Health and Human Services Office of the Assistant Secretary of Health, the RAND Corporation found there are 86 emerging or recently emerged pathogens that threaten the safety of the blood supply. The threat posed by these emerging infectious diseases exhibits the need to plan for managing potential outbreaks.

In particular, Grifols is supportive of the provisions in H.R. 6378 to aid the development and appropriate utilization of multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material; as well as the provisions aimed at strengthening the U.S. blood supply:

Requiring a report on the adequacy of the national blood supply

Establish guidelines, in consultation with health care providers—including blood banks, relating to emergency preparedness which consider the needs of the blood supply, taking into account resiliency, geographic and rural considerations, as well as the financial implications of implementing such guidelines

Seeking input from all blood supply stakeholders in the development of emergency preparedness guidelines will help strengthen the public health infrastructure by ensuring that the unique needs of the blood supply are met.

In the interests of U.S. public health, we encourage Congress to pass H.R. 6378 to ensure a robust response to public health threats.

Sincerely,

CHRISTOPHER HEALEY,
Vice President.

Mrs. BROOKS of Indiana. Mr. Speaker, I include the following letters in the RECORD.

JULY 18, 2018.

Hon. SUSAN BROOKS,
Washington, DC.
Hon. ANNA ESHOO,
Washington, DC.

DEAR REPRESENTATIVES BROOKS AND ESHOO: I am writing on behalf of Roche Diagnostics Corporation in support of H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. Congratulations on advancing this legislation out of the Energy and Commerce Committee.

We applaud your efforts in improving the nation's overall preparedness and response capabilities. We especially appreciate the Committee's recognition that diagnostics can play a key role in responding to public health and medical emergencies.

We look forward to continuing to work with you as this legislation advances in Congress.

Sincerely,

RUSSELL C. RING,
Vice President, Government Affairs,
Roche Diagnostics Corporation.

STRATEGIC HEALTH INFORMATION EXCHANGE COLLABORATIVE,
July 18, 2018.

REPS. BROOKS AND ESHOO AND MEMBERS OF THE ENERGY AND COMMERCE COMMITTEE: On behalf of the Strategic Health Information Exchange Collaborative (SHIEC), which represents more than 60 Health Information Exchanges (HIEs) across the nation, thank you for your leadership on the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPAI). SHIEC HIEs have played an important role across the country and have a strong interest in emergency preparedness and disaster relief. SHIEC HIEs have demonstrated the important role they play in federal, state, and local governments. In 2017 SHIEC HIEs in Texas partnered with local providers and patients to access critical medical information in the wake of Hurricane Harvey, and SHIEC HIEs in New York helped to thwart a ransomware attack and safeguard patient information. SHIEC is a recognized leader in medical record interoperability via the Patient Centered Data Home. This initiative allows patients, no matter where they are—whether caught up in emergencies while traveling or displaced by disasters—access to their medical information when and where they need it.

SHIEC is pleased with the proposed direction for this reauthorization of PAHPAI, particularly the broadened scope of Title II regarding ''Optimizing State and Local All-Hazards Preparedness and Response.'' State and local agencies and hospitals are not the only healthcare stakeholders during a crisis. There are many entities that should be consulted in emergency-planning. Addressing the problems and solutions more broadly allows state and local agencies and hospitals to better prepare and handle disasters.

To this end SHIEC applauds the Committee's inclusion of not just the brick and mortar infrastructure, but also the ''technological infrastructure'' while developing guidelines and protocols. SHIEC is also happy to see the broad reference to ''healthcare or subject matter experts'' which replaces a more restrictive reference to healthcare providers and agencies.

SHIEC recommends inclusion of HIEs specifically. As the data trustees in a community, SHIEC HIEs offer vital services to support a community in crisis. Awareness and realization of this full benefit has yet to be achieved in some areas. Without inclusion of clarifying language, SHIEC is concerned HIEs may still be left out of planning. SHIEC hopes however, that the broader, more inclusive language that the Committee has proposed will be expansive enough to ensure HIEs a seat at the emergency preparedness and disaster relief table.

Thank you,

KELLY HOOVER THOMPSON,
CEO.

TAKEDA,
Cambridge, MA, July 20, 2018.

Hon. GREG WALDEN,
Chariman, House Energy and Commerce Committee,
House of Representatives,
Washington, DC.
Hon. SUSAN W. BROOKS,
House of Representatives,
Washington, DC.
Hon. FRANK PALLONE, JR.,
Ranking Member, House and Energy and Commerce Committee,
House of Representatives,
Washington, DC.
Hon. ANNA G. ESHOO,
House of Representatives,
Washington, DC.

CHAIRMAN WALDEN, RANKING MEMBER PALLONE, AND REPRESENTATIVES BROOKS AND ESHOO: Takeda Vaccines appreciates the opportunity to support H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. The legislation contains important provisions to improve the nation's ability to respond to public health emergencies and to accelerate research and development of medical countermeasures. Of particular note is the creation of the Emerging Infectious Disease Program within the Biomedical Advanced Research and Development Authority (''BARDA'') that will support research and development and manufacturing infrastructure with respect to emerging infectious diseases.

Takeda is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. In addition to its efforts in oncology, gastroenterology, and neuroscience, Takeda is actively engaged in the research and development of vaccines including one for the deadly Zika virus. We appreciate the collaboration with BARDA to advance innovation in this disease state.

Takeda applauds the action of the House Energy and Commerce Committee to pass H.R. 6378 on July 18, 2018, and thanks the Members and staff for their hard work on this critical bill.

Sincerely,

RAJEEV VENKAYYA, M.D.,
President, Global Vaccines Business Unit,
Takeda Pharmaceutical Company Limited.

TRAUMA CENTER ASSOCIATION OF AMERICA,
July 24, 2018.

Hon. GREG WALDEN,
Chairman, House Committee on Energy & Commerce,
Washington, DC.
Hon. SUSAN BROOKS,
House of Representatives,
Washington, DC.
Hon. FRANK PALLONE, JR.,
Ranking Member, House Committee on Energy & Commerce,
Washington, DC.
Hon. ANNA ESHOO,
House of Representatives,
Washington, DC.

DEAR CHAIRMAN WALDEN, RANKING MEMBER PALLONE, REP. BROOKS AND REP. ESHOO: The Trauma Center Association of America (''TCAA'') strongly supports H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018. We applaud your bipartisan leadership in developing this legislation that will help improve and strengthen the preparedness and response capabilities of our nation's trauma care system.

We appreciate your willingness to work with TCAA and our members as you crafted this important piece of legislation. Specifically, we are pleased to see that the bill reauthorizes federal grant funding to support the core missions of trauma centers to offset the cost of activities such as patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel, trauma staff recruitment and retention, ensuring surge capacity, and trauma-related emotional and mental health services.

Additionally, TCAA has long advocated for the MISSION ZERO Act, and we strongly support the inclusion of language to establish a grant program for military-civilian partnerships in trauma care that will allow both sectors to benefit from the others' expertise and experience. This will benefit patients both on and off the battlefield and we look forward to continuing to work with you to implement this program.

Finally, we were pleased to see that the bill requires the development of guidelines, and the authorization of a demonstration program, to promote coordination and surge capacity among regional systems of hospitals and other public health facilities during a public health emergency. This will help improve our nation's response capabilities and give more patients access to high quality trauma care.

We look forward to passage of H.R. 6378 and continued work with the Senate to ensure that this legislation becomes law. Again, thank you for your hard work and commitment to preparing and equipping our

healthcare system for future disasters and public health emergencies.

EILEEN WHALEN, MHA, BSN, RN,
Chair, Board of Directors. Trauma Center Association of America.
JENNIFER WARD, MBA, BSN, RN,
President, Trauma Center Association of America.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Indiana (Mrs. BROOKS) that the House suspend the rules and pass the bill, H.R. 6378, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill to reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.''.

A motion to reconsider was laid on the table.

NUCLEAR UTILIZATION OF KEYNOTE ENERGY ACT

Mr. OLSON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1320) to amend the Omnibus Budget Reconciliation Act of 1990 related to Nuclear Regulatory Commission user fees and annual charges, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1320

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Nuclear Utilization of Keynote Energy Act''.

SEC. 2. NUCLEAR REGULATORY COMMISSION USER FEES AND ANNUAL CHARGES THROUGH FISCAL YEAR 2020.

(a) IN GENERAL.—Section 6101(c)(2)(A) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 2214(c)(2)(A)) is amended—

(1) in clause (iii), by striking ''and'' at the end;

(2) in clause (iv), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(v) amounts appropriated to the Commission for the fiscal year for activities related to the development of a regulatory infrastructure for advanced nuclear reactor technologies (which may not exceed $10,300,000).''.

(b) REPEAL.—Effective October 1, 2020, section 6101 of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 2214) is repealed.

SEC. 3. NUCLEAR REGULATORY COMMISSION USER FEES AND ANNUAL CHARGES FOR FISCAL YEAR 2021 AND EACH FISCAL YEAR THEREAFTER.

(a) ANNUAL BUDGET JUSTIFICATION.—

(1) IN GENERAL.—In the annual budget justification submitted by the Commission to Congress, the Commission shall expressly identify anticipated expenditures necessary for completion of the requested activities of the Commission anticipated to occur during the applicable fiscal year.

(2) RESTRICTION.—The Commission shall, to the maximum extent practicable, use any funds made available to the Commission for a fiscal year for the anticipated expenditures identified under paragraph (1) for the fiscal year.

(3) LIMITATION ON CORPORATE SUPPORT COSTS.—With respect to the annual budget justification submitted to Congress, corporate support costs, to the maximum extent practicable, shall not exceed the following percentages of the total budget authority of the Commission requested in the annual budget justification:

(A) 30 percent for each of fiscal years 2021 and 2022.

(B) 29 percent for each of fiscal years 2023 and 2024.

(C) 28 percent for fiscal year 2025 and each fiscal year thereafter.

(b) FEES AND CHARGES.—

(1) ANNUAL ASSESSMENT.—

(A) IN GENERAL.—Each fiscal year, the Commission shall assess and collect fees and charges in accordance with paragraphs (2) and (3) in a manner that ensures that, to the maximum extent practicable, the amount assessed and collected is equal to an amount that approximates—

(i) the total budget authority of the Commission for that fiscal year; less

(ii) the budget authority of the Commission for the activities described in subparagraph (B).

(B) EXCLUDED ACTIVITIES DESCRIBED.—The activities referred to in subparagraph (A)(ii) are the following:

(i) Any fee-relief activity, as identified by the Commission.

(ii) Amounts appropriated for the fiscal year to the Commission—

(I) from the Nuclear Waste Fund established under section 302(c) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10222(c));

(II) for implementation of section 3116 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 (50 U.S.C. 2601 note; Public Law 108–375);

(III) for the homeland security activities of the Commission (other than for the costs of fingerprinting and background checks required under section 149 of the Atomic Energy Act of 1954 (42 U.S.C. 2169) and the costs of conducting security inspections);

(IV) for the Inspector General services of the Commission provided to the Defense Nuclear Facilities Safety Board;

(V) for the partnership program with institutions of higher education established under section 244 of the Atomic Energy Act of 1954 (42 U.S.C. 2015c); and

(VI) for the scholarship and fellowship programs under section 243 of the Atomic Energy Act of 1954 (42 U.S.C. 2015b).

(iii) Costs for activities related to the development of regulatory infrastructure for advanced nuclear reactor technologies (which may not exceed $10,300,000).

(C) EXCEPTION.—The exclusion described in subparagraph (B)(iii) shall cease to be effective on January 1, 2026.

(D) REPORT.—Not later than December 31, 2023, the Commission shall submit to the Committee on Appropriations and the Committee on Environment and Public Works of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report describing the views of the Commission on the continued appropriateness and necessity of funding for the activities described in subparagraph (B)(iii).

(2) FEES FOR SERVICE OR THING OF VALUE.—In accordance with section 9701 of title 31, United States Code, the Commission shall assess and collect fees from any person who receives a service or thing of value from the Commission to cover the costs to the Commission of providing the service or thing of value.

(3) ANNUAL CHARGES.—

(A) IN GENERAL.—Subject to subparagraph (B) and except as provided in subparagraph (D), the Commission may charge to any licensee or certificate holder of the Commission an annual charge in addition to the fees set forth in paragraph (2).

(B) CAP ON ANNUAL CHARGES OF CERTAIN LICENSEES.—

(i) OPERATING REACTORS.—The annual charge under subparagraph (A) charged to an operating reactor licensee, to the maximum extent practicable, shall not exceed the annual fee amount per operating reactor licensee established in the final rule of the Commission entitled ''Revision of Fee Schedules; Fee Recovery for Fiscal Year 2015'' (80 Fed. Reg. 37432 (June 30, 2015)), as may be adjusted annually by the Commission to reflect changes in the Consumer Price Index published by the Bureau of Labor Statistics of the Department of Labor.

(ii) FUEL FACILITIES.—

(I) IN GENERAL.—The total annual charges under subparagraph (A) charged to fuel facility licensees, to the maximum extent practicable, shall not exceed an amount that is equal to the total annual fees collected from the fuel facilities class under the final rule of the Commission entitled ''Revision of Fee Schedules; Fee Recovery for Fiscal Year 2016'' (81 Fed Reg. 41171 (June 24, 2016)), which amount may be adjusted annually by the Commission to reflect changes in the Consumer Price Index published by the Bureau of Labor Statistics of the Department of Labor.

(II) EXCEPTION.—Subclause (I) shall not apply if the number of licensed facilities classified by the Commission as fuel facilities exceeds seven.

(III) CHANGES TO ANNUAL CHARGES.—Any change in an annual charge under subparagraph (A) charged to a fuel facility licensee shall be based on—

(aa) a change in the regulatory services provided with respect to the fuel facility; or

(bb) an adjustment described in subclause (I).

(iii) WAIVER.—The Commission may waive, for a period of 1 year, the cap on annual charges described in clause (i) or (ii) if the Commission submits to the Committee on Appropriations and the Committee on Environment and Public Works of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a written determination that the cap on annual charges may compromise the safety and security mission of the Commission.

(C) AMOUNT PER LICENSEE.—

(i) IN GENERAL.—The Commission shall establish by rule a schedule of annual charges fairly and equitably allocating the aggregate amount of charges described in clause (ii) among licensees and certificate holders.

(ii) AGGREGATE AMOUNT.—For purposes of this subparagraph, the aggregate amount of charges for a fiscal year shall equal an amount that approximates—

(I) the amount to be collected under paragraph (1)(A) for the fiscal year; less

(II) the amount of fees to be collected under paragraph (2) for the fiscal year.

(iii) REQUIREMENT.—The schedule of charges under clause (i)—

(I) to the maximum extent practicable, shall be reasonably related to the cost of providing regulatory services; and

(II) may be based on the allocation of the resources of the Commission among licensees or certificate holders or classes of licensees or certificate holders.

(D) EXEMPTION.—Subparagraph (A) shall not apply to the holder of any license for a federally owned research reactor used primarily for educational training and academic research purposes.

(c) PERFORMANCE AND REPORTING.—

(1) IN GENERAL.—The Commission shall develop for the requested activities of the Commission—