H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

TITLE I: STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Section 101: National Health Security Strategy

- Clarifies that the National Health Security Strategy should describe potential public health threats facing our nation and identify the processes to prepare to respond to such threats, consistent with other specified plans.
- Incorporates into the Strategy—
  - A description of the current public health workforce and its capabilities to improve medical surge capacity.
  - Considerations for zoonotic disease and disease outbreaks related to food and agriculture.
  - Global health security and environmental hazards as they relate to domestic public health preparedness and response capabilities.

TITLE II: IMPROVING PREPAREDNESS AND RESPONSE

Section 201: Improving Benchmarks and Standards for Preparedness and Response

- Requires the evaluation of existing performance measures, benchmarks, and standards for two core preparedness and response programs, the Public Health Emergency Preparedness (PHEP) cooperative agreement and the Hospital Preparedness Program (HPP).

Section 202: Amendments to Preparedness and Response Programs

- Reauthorizes the PHEP cooperative agreement through 2023. Clarifies that the PHEP cooperative agreement be administered through the Centers for Disease Control and Prevention and updates requirements for the plans required of all PHEP eligible entities.
- Provides additional flexibility for PHEP and HPP awardees to come into compliance with the failure to meet program benchmarks and standards.
- Requires PHEP grantees to include a description of efforts to incorporate health care facilities (i.e. hospitals, nursing homes, and other long-term care facilities), and critical infrastructure partners (i.e. utility companies) in preparing for a public health emergency in their funding applications.
- Reauthorizes HPP through 2023.

Section 203: Regional Health Care Emergency Preparedness and Response Systems

- Requires the Assistant Secretary for Preparedness and Response (ASPR) to develop guidelines within two years, to inform regional systems of hospitals and health care facilities, to treat patients affected by chemical, biological, radiological, or nuclear (CBRN) threats, including emerging infectious diseases, and improve medical surge capabilities and capacity.
- The guidelines will build on lessons learned from the Ebola virus outbreak in 2014 and will provide a roadmap for regions across the country to best leverage their health system infrastructure in the event of a bioterror attack, an emerging infectious disease outbreak, or a pandemic.

- Allows the ASPR to develop and implement a demonstration project to put the new guidelines developed into practice in regions across the country, which sunsets in 2023.
- Requires the Government Accountability Office (GAO) to report within three years on the progress made towards the implementation of the guidelines by hospitals and health care facilities, and requires subsequent recommendations to address challenges faced during implementation.
- Requires HPP grantees to report on implementation efforts aimed at meeting the capability guidelines.
- Incorporates into the National Health Security Strategy a coordinated and flexible approach to regional health care emergency preparedness and response.
- Encourages PHEP grantees to coordinate with regional health care emergency response capabilities.
- Prioritizes awarding HPP grants to entities that will enhance coordination among one or more facilities in a regional health care emergency system.
- Allows for additional resources authorized under HPP to go toward the new regionalized systems, ensuring existing resources are not taken away from HPP.

Section 204: Military and Civilian Partnership for Trauma Readiness

- Authorizes the Secretary, acting through the ASPR and in consultation with the Secretary of Defense, to award grants to trauma centers to enable military trauma teams to provide trauma care at such centers.
- Requires as a condition of such grants that military trauma providers providing care under such grants be allowed to deploy for military operations or training, and to response to public health emergencies or mass casualty incidents.
- Integrates military trauma providers at such trauma centers into trainings and drills for public health emergencies.
- Calls for reporting to the Secretaries of HHS and Defense by grantees, as well as to Congress by the Secretaries of HHS and Defense.
- Authorizes appropriations through 2023.

Section 205: Public Health and Health Care System Situational Awareness and Biosurveillance Capabilities

- Directs the GAO to conduct a study on federal spending for Centers for Disease Control and Prevention (CDC) activities related to facility development, and improved capacity and biosurveillance capability for responding to bioterrorism and other public health emergencies.
- Updates and improves CDC's biosurveillance capabilities to advance public health situational awareness by:
    - Updating the use of technical and reporting standards, including interoperability standards for data elements submitted to the biosurveillance network.
    - Improving coordination and collaboration within Health and Human Services (HHS) and across federal agencies and departments through the exchange of data in the biosurveillance network to better inform the situational awareness necessary to monitor, identify, and respond to CBRN threats.

- Convening a public meeting for public and private stakeholders to improve the development and function of the biosurveillance network.
- Updating the strategy and implementation plan for the biosurveillance network according to input from experts, and requiring the Secretary to submit such updates to Congress within two years.
- Establishing an annual budget plan to ensure efficient and effective utilization of resources for the development and improvement of the biosurveillance network.
- Improving coordination with the intelligence community to ensure that the design and capabilities of the network align with the threats facing our nation.

- Authorizes the Secretary to appoint up to 30 specialists at the CDC with expertise in capabilities related to biosurveillance, such as experts in informatics and data analytics.
- Requires the GAO to evaluate and report on activities related to the development and improvement of the biosurveillance network and to provide subsequent recommendations.
- Reauthorizes biosurveillance and situational awareness programs through 2023.
- Requires a report on the state of Federal biological threat detection efforts.

Section 206: Strengthening and Supporting the Public Health Emergency Rapid Response Fund

- To more immediately address the needs resulting from a public health emergency, improves the existing Public Health Emergency Fund (PHEF) by identifying key activities for which PHEF dollars may be used in the context of immediate support for the response activities for a public health emergency or prior to a potential public health emergency.
- Requires the Secretary as well as GAO to conduct a review of the PHEF, including policies that may be needed to improve the PHEF (in the case of the Secretary) and the resources available in such fund and the ability to use such resources during a public health emergency (in the case of GAO) and submit such report to Congress.

Section 207: Improving All-Hazards Preparedness and Response by Public Health Emergency Volunteers

- Further encourages states to develop and implement programs and policies to allow for the licensure of medical professionals to enable them to cross state lines during a public health emergency.
- Encourages states to develop mechanisms to improve the enrollment in, and availability of information regarding, opportunities for volunteer health care professionals seeking to provide medical services during public health emergencies.
- Incorporates into PHEP entities' All-Hazards Public Health Emergency Preparedness and Response Plan a description of how they improve enrollment and coordination of health care professionals seeking to provide medical services during public health emergencies. Clarifies that National Disaster Medical System, Medical Reserve Corps members, and individual practitioners are eligible to enroll in the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP).
- Advises the Secretary to make public the ways in which states are waiving licensing requirements for health professional volunteers during a public health emergency in order to encourage state and individual participation in ESAR-VHP.
- Reauthorizes ESAR-VHP through 2023.

Section 208: Clarifying State Liability Law for Volunteer Health Care Professionals

- Clarifies the application of state liability law for health care professionals who are members of the Medical Reserve Corps or included in the Emergency System for Advance Registration of Volunteer Health Professionals.
- For such an individual providing health care services in a state with a public health emergency, a major declared disaster or a national emergency, under certain conditions, applies the liability laws of the state for which the emergency has been determined and in which the service is being provided.
- Requires a GAO report on several aspects of health care providers credentialed by in the Emergency System for Advance Registration of Volunteer Health Professionals or state authorities.

Section 209: Report on Adequate National Blood Supply

- Requires a report with recommendations to address challenges with the national blood supply including challenges with recruitment of donors, maintaining the adequacy of the blood supply during a public health emergency, and efforts to promote innovative technologies to improve the blood supply.

Section 210: Report on the Public Health Preparedness and Response Capabilities and Capacities of Hospitals, Long-term Care Facilities, and Other Health Care Facilities

- Requires a report on the public health preparedness and response capabilities for health care facilities, including a review of the effectiveness benchmarks and standards for preparedness programs, an identification of gaps in such benchmarks and standards, and an evaluation of coordination critical infrastructure entities and environmental health agencies.

TITLE III. REACHING ALL COMMUNITIES

Section 301: Strengthening and Assessing the Emergency Response Workforce

- Recent public health emergencies have strained the public health emergency workforce and have highlighted gaps in workforce preparedness. To address these challenges, this section:
  - Includes greater flexibility in pre-positioning response teams in advance of a public health emergency or potential public health emergency.
  - Requires a joint review of the National Disaster Medical System and an assessment of our medical surge capacity relating to the availability of public health workforce for both a widespread and multiple public health emergencies at one time.
  - Improves communication with Congress by requiring the Secretary to notify Congress when the NDMS workforce is insufficient to address a public health emergency, including information on the effect such insufficiencies will have and potential ways to address the issue.
  - Bolsters hiring authorities to allow for faster onboarding of NDMS to decrease the shortage in the health care emergency response workforce.
  - Extends death benefits for NDMS participants that are allotted to other public safety officers, including FEMA volunteers through 2021.

- Strengthens the recruitment of highly qualified providers to the Epidemic Intelligence Service (EIS) by extending the option of loan repayment for EIS program participants.
- Requires a GAO report on the capabilities and capacity of the volunteer health care workforce, gaps in such workforce, and recommendations for addressing the gaps.

- Reauthorizes the National Disaster Medical System through 2023.
- Reauthorizes the Medical Reserve Corps through 2023.

Section 302: Health System Infrastructure to Improve Preparedness and Response

- Building from lessons learned in previous public health emergencies, this section encourages the ASPR to coordinate with public and private-sector partners that provide critical supplies or information to an affected area during a public health emergency or emergency or major disaster declared by the President under the Stafford Act or National Emergencies Act to assist with the response.
- Requires the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to incorporate the need for certain medical supplies to be used with medical countermeasures (MCM) in MCM enterprise planning.
- Directs the Secretary to consider manufacturing capacity and outside sources of medical supplies when replenishing products in the Strategic National Stockpile (SNS).
- Authorizes the ASPR to conduct a study on issues with the potential to adversely affect the handling and rapid delivery of medical countermeasures.

Section 303: Considerations for At-Risk Individuals

- Updates and aligns the term "at-risk individual" across the PAHPA framework to improve considerations, ensure consistency in considerations, and provide clarity throughout the framework.
- Encourages the director of at-risk individuals to incorporate appropriate data and information relevant to detecting emerging public health threats that may affect at-risk individuals, such as pregnant and postpartum women and infants into the existing situational awareness and biosurveillance network at the CDC.

Section 304: Improving Emergency Preparedness and Response Considerations for Children

- Codifies and continues the work of the Children's Preparedness Unit at the CDC to ensure the needs of children are taken into consideration when preparing for and responding to public health emergencies.

Section 305: National Advisory Committees on Disasters

- Reauthorizes the National Advisory Committee on Children and Disasters through 2023.
- Authorizes a National Advisory Committee on Seniors and Disasters through 2023.
- Authorizes a National Advisory Committee on Individuals with Disabilities in Disasters through 2023.
- Requires the advisory committees to coordinate duties and activities to address the overlapping needs of such individuals and reduce duplicate efforts.

Section 306: Guidance for Participation in Exercises and Drills

- Requires the Secretary to issue final guidance on the participation of federally funded public health personnel in drills and operational exercises for public health emergency preparedness and response.

TITLE IV: PRIORITIZING A THREAT-BASED APPROACH

Section 401: Assistant Secretary for Preparedness and Response

- Clarifies the congressional intent for the ASPR to utilize experience related to biodefense, medical countermeasures, and emergency preparedness and response.
- Encourages the ASPR to coordinate with the intelligence community, and defense and public health agencies in conducting his or her work to address threats and develop and strengthen our emergency preparedness and response framework.
- Authorizes funding for the Assistant Secretary for Preparedness and Response to implement strategic initiatives or activities related to preparedness and response to pandemic influenza threats.

Section 402: Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- Codifies the PHEMCE, an entity comprised of heads of relevant federal agencies to inform the direction of research, development, stockpiling, utilization, and procurement of MCMs for the SNS, including considerations for deployment and distribution of MCMs.

Section 403: Strategic National Stockpile

- Requires that the Secretary collaborate with both the ASPR and the CDC in the Secretary's management of the stockpile.
- Provides additional direction and a threat-based focus for the existing annual review of the SNS.
- Requires additional information on SNS procurement and replenishment decisions, as well as advanced planning for deployment, distribution, and dispensing for additions to the SNS.
- Requires GAO to review the Secretary's processes and decisions related to procurement of countermeasures for the stockpile and any changes in the federal organizational management of the SNS.
- Reauthorizes the SNS through 2023.

Section 404: Preparing for Pandemic Influenza, Antimicrobial Resistance, and Other Significant Threats

- Provides authorities for 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.
- These strategic initiatives will accelerate and support advanced research, development, and procurement of countermeasures to address:
    - Threats for which no countermeasure exists, or which may become resistant to current countermeasures or existing countermeasures may be rendered ineffective.
    - Threats that consistently exist or are continually circulating in a human or animal population and have significant potential to become a pandemic, such as pandemic influenza.

- Certain threats resulting from exposure to a CBRN agent and which may present increased complications in treating a countermeasure resistant disease or condition during a public health emergency, including antimicrobial resistant pathogens.
- Authorizes an Emerging Infectious Disease Program to support advanced research and development activities for qualified pandemic or epidemic products with respect to an emerging infectious disease.

Section 405. Reporting on the Federal Select Agent Program

- Requires the Secretary to report on the implementation of recommendations from the Federal Experts Security Advisory Panel and the Fast Track Action Committee regarding improvements to the Select Agent Program.

TITLE V: INCREASING COMMUNICATION IN MCM ADVANCED RESEARCH AND DEVELOPMENT

Section 501: Medical Countermeasure Budget Plan

- Updates the Countermeasure Budget Plan to include considerations for manufacturing capabilities and capacity for MCMs, information on new and innovative technologies that may support the research and development of MCMs, to improve the communication on areas of priority for MCM development, and provide information related to potential the deployment, distribution, and utilization of medical countermeasures.

Section 502: Material Threat and Medical Countermeasure Notifications

- Requires the Secretaries of HHS and Department of Homeland Security (DHS) to notify the Health, Education, Labor and Pensions Committee of the Senate, the Security and Government Affairs Committee of the Senate, and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives of current material threat determinations on an annual basis, and promptly notify Congress each time there is a change to such determinations.
- Requires the Secretary to notify a manufacturer of a MCM within 90 days, regarding the Secretary's decision to award, extend, renew or terminate agreements related to the purchase of MCMs for the stockpile.

Section 503: Availability of Regulatory Management Plans

- Requires the Food and Drug Administration (FDA) to post on the Internet the processes and information necessary for potential MCM sponsors to apply for a regulatory management plan to raise awareness of the use of the plans for MCMs.

Section 504: BARDA and the Bioshield Special Reserve Fund

- Reauthorizes BARDA through 2023.
- Reauthorizes the BioShield Special Reserve Fund through 2028.

Section 505. Additional Strategies for Combating Antibiotic Resistance.

- Codifies the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to advise the Secretary on efforts to reduce or combat antibiotic-resistant bacteria that may present a public health threat and provide input to improve capabilities to prevent, diagnose, mitigate, or treat such resistance.

TITLE VI: ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

Section 601: Administration of Countermeasures

- Clarifies BARDA's ability to use existing resources toward the development of technologies intended to assist in the administration of countermeasures.

Section 602: Updating Definitions of Other Transactions

- Clarifies the authority of the BARDA Director to utilize other transactions authorities to further the advanced research and development of medical countermeasures.

Section 603: Medical Countermeasure Master Files

- Establishes a clear process for submitting information and data on technologies into a Master File that may be incorporated into a future application to support a MCM product. A product sponsor, either the submitter of information or another person with right of reference, may utilize this information and data as a part of their MCM application, and build upon that data for future MCM applications.
- Requires FDA to notify the Master File holder when the agency has referenced the technology in the Master File – clarifying that the same data and information can support future MCM applications.
- Requires FDA to publish draft guidance, within three years, on the reliance and use of data and information included in the Master Files to support and accelerate the development of countermeasures.

Section 604: Animal Rule Report

- Requires the GAO to consult federal agencies, manufacturers, and other biodefense stakeholders to inform a report within three years on the use of the animal rule in the development of MCMs, and if applicable make recommendations to support and speed the research and development of MCMs.

Section 605: Review of the Benefits of Genomic Engineering Technologies and Their Potential Role in National Security

- Requires the Secretary of HHS to convene a meeting with federal partners and private entities to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security.
- Not later than 270 days after such meeting, the ASPR will issue a report detailing the discussion and providing recommendations to utilize innovation in this technology to advance national health security.

Section 606: Report on Vaccines Development
• Requires a report on previous efforts to coordinate with other countries during public health emergencies to conduct advanced research and development of qualified pandemic or epidemic products, including the development of products through public-private partnerships.
Section 607: Strengthening Mosquito Abatement for Safety and Health (SMASH)
• Reauthorizes critical public health tools that support states and localities in their mosquito surveillance and control efforts, especially those linked to vector-borne diseases like the Zika virus. • Renews epidemiology-laboratory capacity grants administered by CDC that provide support for surveillance and response capabilities for infectious diseases at the local level.
TITLE VII: REAUTHORIZATIONS AND TECHNICAL CHANGES
Section 701: Reauthorizations and Extensions
• Reauthorizes funding for influenza vaccine tracking and distribution during an influenza pandemic. • Reauthorizes the temporary reassignment authority through 2023. • Reauthorizes the MCM innovation partner through 2023, to align with the authorized timelines in this Act. • Extends the limited antitrust exemption. • Clarifies the limitations on the disclosure of certain scientific or technical information developed during medical countermeasure research.
Section 702: Location of Materials in the Stockpile
• Updates and clarifies the limitations on the disclosure of certain information pertaining to the Strategic National Stockpile with the potential to affect national security.
Section 703: Cybersecurity
• Requires the development of a national strategy for public health preparedness and response to address cybersecurity threats that present a threat to national health security. • Clarifies the role of the ASPR as it relates to cyber incidents that present a threat to national health security.
Section 704: Technical Changes
• Technical amendments to the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.
Section 705: Formal Strategy for Reunification
• Requires a formal strategy to reunite each child with their parent or guardian where they have been separated as a result of the “zero tolerance” policy.
Section 706: Report on Reunification

• Requires a report on the status of the work conducted by the ASPR to reunite each child with their parent or guardian where they have been separated as a result of the "zero tolerance" policy.
Section 707: Technical Correction
• This technical correction to section 704 of the FDA Reauthorization Act of 2017, will ensure medical device manufacturers can obtain "certificates to foreign governments" whether they are located inside or outside the U.S., as was intended by Congress.
Section 708: Savings Clause
• Sets forth that nothing in this Act reduces or limits authorities vested in other Federal Agencies.

Suspend the Rules And Pass the Bill, H.R. 6378, With Amendments

(The amendments strike all after the enacting clause and insert a new text and a new title)

115TH CONGRESS
2D SESSION

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.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2018

Mrs. BROOKS of Indiana (for herself, Ms. ESHOO, Mr. WALDEN, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, and Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

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

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''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 jurisdic-

tion 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 accu-

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

(1) in paragraph (5)—

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

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

(C) by striking ''2008'' and inserting ''2019''; and

(2) 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.''.

(b) 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 ''prepared-

ness 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''.

(c) 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)).''.

(d) 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 sec-

tion 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, radio-

logical, 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, 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, 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 partici-

pating 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 Re-

authorization 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 Informa-

tion 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; stake-

holders 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 Pan-

demic 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 ca-

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

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

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

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

(ii) in subparagraph (B)—

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

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

(iii) in subparagraph (C)—

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

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

(iv) by adding at the end the following:

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

(H) by adding at the end the following:

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

(5) in subsection (d)—

(A) in paragraph (1)—

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

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

(B) in paragraph (2)—

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

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

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

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

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

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

(6) by redesignating subsections (f) and (g) as subsections (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 Cen-

ters 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 capa-

bilities, 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, in-

cluding 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 Ad-

vance 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 authori-

ties 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 haz-

ards, 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 sub-

mit 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 re-

sponse 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 emer-

gency, 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 Sec-

retary 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 re-

spect 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 shall ensure activities 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(f) 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 (in-

cluding 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 fund-

ing 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 Comp-

troller 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), or 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 (f)(2) of section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), as redesignated by section 404, 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 'Combatting 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 ''plat-

form 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 medical countermeasure master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information within a medical countermeasure master file 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 devel-

oping 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 De-

velopment 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 decisionmaking with respect to medical countermeasures.

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

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

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

(2) manufacturers involved in the research and development of medical countermeasures to address biological, chemical, radiological, 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) in subsection (b), by striking ''2010 through 2013'' and inserting ''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 (g)(1) of section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), as redesignated by section 404, 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 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 7, 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 shall submit to the Committee on Energy and Commerce of the House of Representatives 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.

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

TAM18650 S.L.C.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 2852

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

SEC. 2. REFERENCES IN ACT.

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

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

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

(1) in subsection (a)—

(A) in paragraph (1)—

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

(ii) by striking the second sentence and inserting the following: "Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with the national preparedness goal (as described in section 504(a)(19) of the Homeland Security Act of 2002), the National Incident Management System (as

defined in section 501(7) of such Act), and the National Response Plan developed pursuant to section 504 of such Act, or any successor plan.";

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

(C) in paragraph (3)—

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

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

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

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

(2) in subsection (b)—

(A) in paragraph (2)—

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

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

(iii) by adding at the end the following:

"(E) Response to environmental hazards.";

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

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

(D) by adding at the end the following:

"(9) ZOONOTIC DISEASE, FOOD, AND AGRICULTURE.—Improving coordination among Federal, State, local, tribal, and territorial entities (including through consultation with the Secretary of Agri-

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

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

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

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

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

"(k) EVALUATION.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and

All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

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

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

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

"(C) a description of amounts received by eligible entities, as described in subsection (b) and section 319C–2(b), and amounts received

by sub-recipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

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

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

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS.

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

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

(2) in subsection (b)(2)(A)—

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

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

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

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

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

(1) in subsection (a)—

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

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

(2) in subsection (b)(1)(A)—

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

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

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

"(i) consisting of—"; and

(D) by adding at the end the following:

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

(c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZATION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking "$641,900,000 for fiscal year 2014" and all that follows through the period at the end and inserting "$685,000,000 for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)).".

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

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

"(1) IN GENERAL.—

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

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

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

"(ii) RESERVATIONS CONTINGENT ON CONTINUED APPROPRIATIONS 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 (42 U.S.C. 243 et seq.) is amended by inserting after section 319C–2 the following:

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

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

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

fairs, 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 sup-

ply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

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

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

"(D) in a manner that allows for disease containment (within the meaning of section 2802(b)(2)(B)), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or

health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

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

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

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

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

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

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

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

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

"(d) TECHNICAL ASSISTANCE.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and

Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assistance and consultation towards meeting the guidelines described in subsection (b).

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

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

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

"(f) GAO REPORT TO CONGRESS.—

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

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

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

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

"(B) recommendations to reduce gaps in incentives for regional health partners, including hospitals and health care facilities to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a), which

may include consideration of facilities participating in programs under section 319C–2, programs under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

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

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

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

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

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

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

"(F) the Secretary of Veterans Affairs; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(a) MILITARY TRAUMA TEAM PLACEMENT PROGRAM.—

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

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

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

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

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

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

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

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

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

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

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

"(c) GRANT REQUIREMENTS.—

"(1) DEPLOYMENT AND PUBLIC HEALTH EMERGENCIES.—As a condition of receipt of a grant under this section, a grant recipient shall agree to

allow military trauma care providers providing care pursuant to such grant to—

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

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

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

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

"(e) REPORTING REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

"(E) efforts to incorporate military trauma care providers into operational exercises and training and drills for public health emergencies; and

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

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

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

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

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

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

"(2) ELIGIBLE HIGH ACUITY TRAUMA CENTER.—The term 'eligible high acuity trauma center' means a Level I trauma center that satisfies each of the following:

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

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

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

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

"(i) affiliated with a medical school;

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

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

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

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

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

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

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appro-

priated $6,800,000 for each of fiscal years 2019 through 2023.".

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

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

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

(2) in subsection (a)—

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

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

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

(D) by adding at the end the following:

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

(3) in subsection (b)—

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

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

(C) in paragraph (2)—

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

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

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

"(3) STANDARDS.—

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

Department of Health and Human Services, in a manner that does not compromise national security.

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

(4) in subsection (c)—

(A) in paragraph (1)—

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

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

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

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

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

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

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

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

(C) in paragraph (3)—

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

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

(I) by inserting "immunization information 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 subpara-

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

(D) in paragraph (5)—

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

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

"(A) IN GENERAL.—In establishing";

(iii) by adding at the end the following:

"(B) PUBLIC MEETING.—

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

providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

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

calities, tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.";

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

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

"(f) PERSONNEL AUTHORITIES.—

"(1) SPECIALLY QUALIFIED PERSONNEL.—In addition to any other personnel authorities, to carry out subsection (b) and subsection (c), the Secretary may—

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

"(B) compensate individuals appointed under subparagraph (A) in the same manner

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

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

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

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

applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.".

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

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

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

(1) in subsection (b)—

(A) in paragraph (1)—

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

(ii) by inserting "The Secretary shall plan for the expedited distribution of funds

to appropriate agencies and entities." after the first sentence;

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

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

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

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

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

"(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section

319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

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

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

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

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

"(4) REVIEW.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Assist-

ant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section, and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

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

(2) in subsection (c)—

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

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

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

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

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

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

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

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

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

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

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

"(1) is responding to a public health emergency declared under section 319(a) during the initial 90-day period of the public health emergency determination (excluding any period covered by a renewal of such determination);

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

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

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

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

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

"(3) prior to the rendering of such act or omission, was authorized by the State's authorization of a deploying State's Emergency System for Advance Registration of Volunteer Health Professionals described in section 319I or the Medical Reserve Corps established under section 2813, to provide health care services,

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

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

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

any State other than the State liability laws to which such individual is subject pursuant to such subsection.

"(d) DEFINITIONS.—In this section:

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

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

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

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

(b) EFFECTIVE DATE.—

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

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

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

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

(2) the number of health care providers who are credentialed to provide services during the period of a public health emergency declaration, including those who are credentialed though programs established in the verification network pursuant to such section 319I and those credentialed by authorities within the State in which the emergency occurred;

(3) the average time to verify the credentials of a health care provider during the period of a public health emergency declaration, including the average time pursuant to the verification network under such section 319I and for an individual's credentials to be verified by an authority within the State; and

(4) the States' Emergency System for Advance Registration of Volunteer Health Professionals volunteer program, including whether physician or medical groups, associations, or other relevant pro-

vider organizations utilize such program for purposes of volunteering during public health emergencies.

TITLE III—REACHING ALL COMMUNITIES

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

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

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

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

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

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

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

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

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

"(iii) the capacity of the workforce described in clause (ii) to respond to all hazards, including capacity to simultaneously respond to multiple public health emer-

gencies and the capacity to respond to a nationwide public health emergency;

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

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

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

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

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

"(4) NOTIFICATION.—Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster response personnel of such System is insufficient to address a public health emergency or potential public health emergency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency, and any identified measures to address such shortage.

"(5) CERTAIN APPOINTMENTS.—

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

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

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

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

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

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

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

(f) NATIONAL DISASTER MEDICAL SYSTEM AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) (42

U.S.C. 300hh–11(g)) is amended by striking "$52,700,000 for each of fiscal years 2014 through 2018" and inserting "$57,400,000 for each of fiscal years 2019 through 2023".

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

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

(a) COORDINATION OF PREPAREDNESS.—Section 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by adding at the end the following: "Such logistical support shall include working with other relevant Federal, State, local, tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including an emergency under section 319, an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or the National Emergencies Act, including by establishing methods to ex-

change critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.".

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

SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.

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

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

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

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

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

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

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

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

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

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

"(b) EXPERTISE.—The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavioral pediatrician, and may also include behavioral scientists, child psychologists, 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. REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

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

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

(2) in subsection (d)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(D) The Commissioner of Food and Drugs.

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

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

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

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

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

"(J) The Secretary of Education.

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

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

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

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

(4) by redesignating subsection (f) as subsection (g);

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

"(f) COORDINATION.—The Secretary shall coordinate activities authorized under this section and section 2811B, in accordance with section 2811B(d)."; and

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

SEC. 306. AUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

Subtitle B of title XXVIII (42 U.S.C. 300hh et seq.) is amended by inserting after section 2811A the following:

"SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

"(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security and the Sec-

retary of Veterans Affairs, shall establish an advisory committee to be known as the National Advisory Committee on Seniors and Disasters (referred to in this section as the 'Advisory Committee').

"(b) DUTIES.—

"(1) IN GENERAL.—The Advisory Committee shall—

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

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

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

"(2) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to the Secretary with respect to seniors and the medical and public health grants and cooperative agree-

ments as applicable to preparedness and response activities under this title and title III.

"(3) MEMBERSHIP.—

"(A) IN GENERAL.—The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

"(B) REQUIRED MEMBERS.—The members appointed under paragraph (1) shall include—

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

"(ii) the Director of the Biomedical Advanced Research and Development Authority;

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

"(iv) the Commissioner of Food and Drugs;

"(v) the Director of the National Institutes of Health;

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

"(vii) the Administrator of the Administration for Community Living;

"(viii) the Administrator of the Federal Emergency Management Agency;

"(ix) the Under Secretary for Health of the Department of Veterans Affairs;

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

"(xi) at least 2 representatives of State, local, territorial, or tribal agencies with expertise in disaster planning, preparedness, response, or recovery; and

"(xii) representatives of such other Federal agencies (such as the Department of Energy and the Department of Homeland Security) as the Secretary determines necessary to fulfill the duties of the Advisory Committee.

"(c) MEETINGS.—The Advisory Committee shall meet not less frequently than biannually.

"(d) ADVISORY COMMITTEE COORDINATION.—

"(1) IN GENERAL.—The Secretary shall coordinate activities authorized under this section and sec-

tion 2811A, and make efforts to reduce unnecessary or duplication of meetings, recommendations, and reporting under such sections. Members of the advisory committees under this section and section 2811A, or their designees, shall meet periodically, and not less than annually, to—

"(A) review the recommendations developed by such committees to coordinate, as appropriate, the implementation of recommendations, in order to reduce gaps, overlap, and duplication of effort in Federal programs or by Federal grantees; and

"(B) align preparedness and response programs or activities to address the dual or overlapping needs of children and seniors and any challenges in preparing for and responding to such needs.

"(2) NOTIFICATION.—The Secretary shall notify the congressional committees of jurisdiction upon the convening of each meeting under paragraph (1), and provide minutes from such meeting not later than 90 days after the meeting.

"(e) SUNSET.—The Advisory Committee shall terminate on September 30, 2023.".

SEC. 307. GUIDANCE FOR PARTICIPATION IN EXERCISES AND DRILLS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance regarding the participation of State, local, tribal, and territorial public health department or agency personnel funded in whole or in part through programs authorized under this Act in drills and operational exercises in order to identify, inform, and address the gaps in and policies related to all-hazards medical and public health preparedness and response, which may include drills and operational exercises that incorporate medical surge capacity planning, medical countermeasure distribution and administration, and preparing for and responding to identified threats for that region. The Secretary shall consult with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies as necessary and appropriate in the development of such guidance. The Secretary shall make the guidance available on the internet website of the Department of Health and Human Services.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

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

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

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

"(I) THREAT AWARENESS.—Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, and other relevant Federal officials, such as the Secretary of Agriculture, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have

the potential to result in a public health emergency.".

SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

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

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

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

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

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

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

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

"(4) The Commissioner of Food and Drugs.

"(5) The Secretary of Defense.

"(6) The Secretary of Homeland Security.

"(7) The Secretary of Agriculture.

"(8) The Secretary of Veterans Affairs.

"(9) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the Secretary determines appropriate.

"(c) FUNCTIONS.—

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

"(A) Establish a process pursuant to section 2811(d)(2)(B) to make recommendations to the Secretary regarding the prioritization of research, development, and procurement of countermeasures, as defined in section 319F–2(c), based on the health security needs of the United States. Such recommendations shall be informed by the National Health Security Strategy pursuant to section 2802, the Strategic National Stockpile review required under section 319F–2(a)(2), the countermeasures

budget plan pursuant to section 2811(b)(7), and an assessment of current national security threats, including chemical, biological, radiological and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

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

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

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

"(2) INPUT.—In carrying out subparagraphs (B) and (C) of paragraph (1), the PHEMCE shall

solicit and consider input from State, local, tribal, and territorial public health departments, as appropriate.".

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

(1) in paragraph (1)—

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

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

(2) in paragraph (2)(J)(v), by striking "one-year period" and inserting "2-year period".

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

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

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

(2) in paragraph (1)—

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

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

(C) by striking the second sentence;

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

"(2) THREAT-BASED REVIEW.—

"(A) IN GENERAL.—The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1, review contents within the stockpile and assess whether such contents are

consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review shall be submitted annually, beginning on March 15, 2019, to the Committee on Health, Education, Labor, and Pensions and the Committee on 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 informa-

tion), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;

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

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

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

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

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

"(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabili-

ties of State and local entities to dispense, distribute, and administer the countermeasure; and

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

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

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

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

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

"(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assist-

ant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies, State, local, tribal, and territorial agencies, and the public and private health care infrastructure, as applicable, taking into account the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;" and

(5) by adding at the end the following:

"(5) GAO REPORT.—

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

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

including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

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

"(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to

procurement, modification, or replenishment;

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

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

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

"(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or re-

views by the Secretary or the Comptroller General; and

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

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

(b) AUTHORIZATION OF APPROPRIATIONS, STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42 U.S.C. 247d–6b(f)(1)) is amended by striking "$533,800,000 for each of fiscal years 2014 through 2018" and inserting "$610,000,000 for each of fiscal years 2019 through 2023".

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

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

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

"(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient ap-

proved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

"(ii) threats that consistently exist or continually circulate and have significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material); and

"(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which

may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.".

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

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

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

"(1) IN GENERAL.—The Secretary"; and

(2) by adding at the end the following:

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

"(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

"(B) CONTINUED UPDATES.—The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.".

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

SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.

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

(1) in the matter preceding subparagraph (A), by striking "March 1" and inserting "March 15";

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

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

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

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

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

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

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

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

"(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;".

SEC. 502. MATERIAL THREAT AND MEDICAL COUNTERMEASURE NOTIFICATIONS.

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

(b) CONTRACTING COMMUNICATIONS.—

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

(2) EXPEDITED AUTHORITIES.—Section 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is amended by adding at the end the following: "Upon award, extension, or termination of any such con-

tract, grant, cooperative agreement, and other transaction, the Secretary shall provide a written notification to the receiving entity that includes a justification for such award, extension, or termination.".

SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT PLANS.

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

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

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

"(3) PUBLICATION.—The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

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

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

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

"(D) a description of the types of development milestones and performance targets that

could be discussed and included in such plans; and

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

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

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

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

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

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

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

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

(2) by striking the second sentence.

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

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

SEC. 601. ADMINISTRATION OF COUNTERMEASURES.

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

SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.

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

"SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

"(a) PURPOSE.—The purpose of this section is to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facili-

tating and encouraging submission of data and information to support such products to master files, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary.

"(b) APPLICABILITY OF REFERENCE.—

"(1) IN GENERAL.—A person may submit data and information to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or a person authorized by the master file holder only in accordance with applicable privacy and confidentiality protocols and regulations.

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

"(c) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

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

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

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

"(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

"(d) SPONSOR REFERENCE.—

"(1) IN GENERAL.—Each incorporation of information or data contained in a master file by reference shall describe the incorporated material in a manner in which the Secretary determines appro-

priate and that permits the review of such information without necessitating resubmission of such information or data. Master files shall be submitted in an electronic format in accordance with section 745A and as specified in applicable guidance.

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

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

"(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE SECRETARY.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified information or data within a master file and the purposes for which such information or data was incorporated by reference if the Secretary has reviewed and relied upon such speci-

fied information or data to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

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

"(1) alter the authority of the Secretary to approve, license, classify, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act; or

"(2) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of information or data previously submitted by a sponsor or any other person that

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

"(g) DEFINITIONS.—In this section:

"(1) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biological product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a re-

quest for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or request for an emergency use authorization under section 564 to support—

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

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

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

(b) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified counter-

measures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through the reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) GUIDANCE.—Not later than 2 years after the after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, qualified pandemic or epidemic products. The Secretary, acting through the Commissioner

of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

SEC. 603. PRIORITY ZOONOTIC ANIMAL DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 512 the following:

"SEC. 512A. PRIORITY ZOONOTIC ANIMAL DRUGS.

"(a) DESIGNATION OF A NEW ANIMAL DRUG AS A PRIORITY ZOONOTIC ANIMAL DRUG.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of an application for approval of a new animal drug under section 512(b)(1) or an application for conditional approval of a new animal drug under section 571, expedite the development and review of such new animal drug if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

"(2) REQUEST FOR DESIGNATION.—The sponsor of a new animal drug may request the Secretary to designate a new animal drug described in para-

graph (1) as a priority zoonotic animal drug. A request for the designation may be made concurrently with, or at any time after, the opening of an investigational new animal drug file under section 512(j) or the filing of an application under section 512(b)(1) or 571.

"(3) DESIGNATION.—

"(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the new animal drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary determines that the new animal drug meets the criteria, the Secretary shall designate the new animal drug as a priority zoonotic animal drug and shall take such actions as are appropriate to expedite the development and review of the application for approval or conditional approval of such new animal drug.

"(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

"(i) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies;

"(ii) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

"(iii) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and

"(iv) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.".

SEC. 604. ANIMAL RULE REPORT.

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

(1) The extent to which advanced development and review of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug Administration, including activities facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal rule, consistent with the recommendations in the animal rule guidance, issued pursuant to section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled "Product Development Under the Animal Rule Guidance for Industry" (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related

to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.

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

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

(4) The extent to which the guidance issued under section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled, "Product Development Under the Animal Rule 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 counter-

measures, including the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Department of Defense;

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

(3) other biodefense stakeholders, as applicable.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a) and recommendations to improve the application and consistency of the requirements under subsections (c) and (d) of section 565 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this

section in a manner that does not compromise national security.

SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGINEERING TECHNOLOGIES AND THEIR POTENTIAL ROLE IN NATIONAL SECURITY.

(a) MEETING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall convene a meeting to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security. Such meeting shall be held in a manner that does not compromise national security.

(2) ATTENDEES.—The attendees of the meeting under paragraph (1)—

(A) shall include—

(i) representatives from the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration; and

(ii) representatives from academic, private, and non-profit entities with expertise in genome engineering technologies, biopharmaceuticals, medicine, or biodefense, and other relevant stakeholders; and

(B) may include—

(i) other representatives from the Department of Health and Human Services, as the Secretary determines appropriate; and

(ii) representatives from the Department of Homeland Security, the Department of Defense, the Department of Agriculture, and other departments, as the Secretary may request for the meeting.

(3) TOPICS.—The meeting under paragraph (1) shall include a discussion of—

(A) the current state of the science of genomic engineering technologies related to national health security, including—

(i) medical countermeasure development, including potential efficiencies in the development pathway and detection technologies; and

(ii) the international and domestic regulation of products utilizing genome editing technologies; and

(B) national security implications, including—

(i) capabilities of the United States to leverage genomic engineering technologies as a part of the medical countermeasure enterprise, including current applicable research, development, and application efforts underway within the Department of Defense;

(ii) the potential for state and non-state actors to utilize genomic engineering technologies as a national health security threat; and

(iii) security measures to monitor and assess the potential threat of genomic engineering technologies and related technologies.

(b) REPORT.—Not later than 180 days after the meeting described in subsection (a) is held, the Assistant Secretary for Preparedness and Response shall issue a report to the congressional committees of jurisdiction on the topics discussed at such meeting, and provide rec-

ommendations, as applicable, to utilize innovations in genomic engineering (including genome editing) and related technologies as a part of preparedness and response activities to advance national health security. Such report shall be issued in a manner that does not compromise national security.

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

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

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

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

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

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

(f) LIMITED ANTITRUST EXEMPTION.—

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

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

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

(C) in subsection (a)(1)—

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

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

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

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

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

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

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

SEC. 702. TECHNICAL AMENDMENTS.

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

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

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

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

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

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

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

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

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