

**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 respond 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.

<b>Section 208: Clarifying State Liability Law for Volunteer Health Care Professionals</b>
<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Section 209: Report on Adequate National Blood Supply</b>
<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Section 210: Report on the Public Health Preparedness and Response Capabilities and Capacities of Hospitals, Long-term Care Facilities, and Other Health Care Facilities</b>
<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>TITLE III. REACHING ALL COMMUNITIES</b>
<b>Section 301: Strengthening and Assessing the Emergency Response Workforce</b>
<ul style="list-style-type: none"> <li>• Recent public health emergencies have strained the public health emergency workforce and have highlighted gaps in workforce preparedness. To address these challenges, this section: <ul style="list-style-type: none"> <li>○ Includes greater flexibility in pre-positioning response teams in advance of a public health emergency or potential public health emergency.</li> <li>○ 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.</li> <li>○ 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.</li> <li>○ Bolsters hiring authorities to allow for faster onboarding of NDMS to decrease the shortage in the health care emergency response workforce.</li> <li>○ Extends death benefits for NDMS participants that are allotted to other public safety officers, including FEMA volunteers through 2021.</li> </ul> </li> </ul>



- 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.

<ul style="list-style-type: none"> <li>○ 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.</li> <li>● 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.</li> </ul>
<b>Section 405. Reporting on the Federal Select Agent Program</b>
<ul style="list-style-type: none"> <li>● 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.</li> </ul>
<b>TITLE V: INCREASING COMMUNICATION IN MCM ADVANCED RESEARCH AND DEVELOPMENT</b>
<b>Section 501: Medical Countermeasure Budget Plan</b>
<ul style="list-style-type: none"> <li>● 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.</li> </ul>
<b>Section 502: Material Threat and Medical Countermeasure Notifications</b>
<ul style="list-style-type: none"> <li>● 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.</li> <li>● 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.</li> </ul>
<b>Section 503: Availability of Regulatory Management Plans</b>
<ul style="list-style-type: none"> <li>● 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.</li> </ul>
<b>Section 504: BARDA and the Bioshield Special Reserve Fund</b>
<ul style="list-style-type: none"> <li>● Reauthorizes BARDA through 2023.</li> <li>● Reauthorizes the BioShield Special Reserve Fund through 2028.</li> </ul>

<b>Section 505. Additional Strategies for Combating Antibiotic Resistance.</b>
<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>TITLE VI: ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES</b>
<b>Section 601: Administration of Countermeasures</b>
<ul style="list-style-type: none"> <li>• Clarifies BARDA’s ability to use existing resources toward the development of technologies intended to assist in the administration of countermeasures.</li> </ul>
<b>Section 602: Updating Definitions of Other Transactions</b>
<ul style="list-style-type: none"> <li>• Clarifies the authority of the BARDA Director to utilize other transactions authorities to further the advanced research and development of medical countermeasures.</li> </ul>
<b>Section 603: Medical Countermeasure Master Files</b>
<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Section 604: Animal Rule Report</b>
<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Section 605: Review of the Benefits of Genomic Engineering Technologies and Their Potential Role in National Security</b>
<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>

<b>Section 606: Report on Vaccines Development</b>
<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>Section 607: Strengthening Mosquito Abatement for Safety and Health (SMASH)</b>
<ul style="list-style-type: none"> <li>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.</li> <li>Renews epidemiology-laboratory capacity grants administered by CDC that provide support for surveillance and response capabilities for infectious diseases at the local level.</li> </ul>
<b>TITLE VII: REAUTHORIZATIONS AND TECHNICAL CHANGES</b>
<b>Section 701: Reauthorizations and Extensions</b>
<ul style="list-style-type: none"> <li>Reauthorizes funding for influenza vaccine tracking and distribution during an influenza pandemic.</li> <li>Reauthorizes the temporary reassignment authority through 2023.</li> <li>Reauthorizes the MCM innovation partner through 2023, to align with the authorized timelines in this Act.</li> <li>Extends the limited antitrust exemption.</li> <li>Clarifies the limitations on the disclosure of certain scientific or technical information developed during medical countermeasure research.</li> </ul>
<b>Section 702: Location of Materials in the Stockpile</b>
<ul style="list-style-type: none"> <li>Updates and clarifies the limitations on the disclosure of certain information pertaining to the Strategic National Stockpile with the potential to affect national security.</li> </ul>
<b>Section 703: Cybersecurity</b>
<ul style="list-style-type: none"> <li>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.</li> <li>Clarifies the role of the ASPR as it relates to cyber incidents that present a threat to national health security.</li> </ul>
<b>Section 704: Technical Changes</b>
<ul style="list-style-type: none"> <li>Technical amendments to the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.</li> </ul>
<b>Section 705: Formal Strategy for Reunification</b>
<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>Section 706: Report on Reunification</b>

- 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)**

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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## 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Pandemic and All-Hazards Preparedness and Advancing  
4 Innovation Act of 2018”.

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

Sec. 1. Short title; table of contents.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY  
STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.

Sec. 202. Amendments to preparedness and response programs.

Sec. 203. Regional health care emergency preparedness and response systems.

Sec. 204. Military and civilian partnership for trauma readiness.

Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.

Sec. 206. Strengthening and supporting the public health emergency rapid response fund.

Sec. 207. Improving all-hazards preparedness and response by public health emergency volunteers.

Sec. 208. Clarifying State liability law for volunteer health care professionals.

Sec. 209. Report on adequate national 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.

TITLE III—REACHING ALL COMMUNITIES

Sec. 301. Strengthening and assessing the emergency response workforce.

Sec. 302. Health system infrastructure to improve preparedness and response.

Sec. 303. Considerations for at-risk individuals.

Sec. 304. Improving emergency preparedness and response considerations for children.

Sec. 305. National advisory committees on disasters.

Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

Sec. 401. Assistant Secretary for Preparedness and Response.

Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.

Sec. 403. Strategic National Stockpile.

Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.

Sec. 405. Reporting on the Federal Select Agent Program.



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

- Sec. 501. Medical countermeasure budget plan.
- Sec. 502. Material threat and medical countermeasure notifications.
- Sec. 503. Availability of regulatory management plans.
- Sec. 504. The Biomedical Advanced Research and Development Authority and the BioShield Special Reserve Fund.
- Sec. 505. Additional strategies for combating antibiotic resistance.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL  
COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
- Sec. 602. Updating definitions of other transactions.
- Sec. 603. Medical countermeasure master files.
- Sec. 604. Animal rule report.
- Sec. 605. Review of the benefits of genomic engineering technologies and their potential role in national security.
- Sec. 606. Report on vaccines development.
- Sec. 607. Strengthening mosquito abatement for safety and health.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Reauthorizations and extensions.
- Sec. 702. Location of materials in the stockpile.
- Sec. 703. Cybersecurity.
- Sec. 704. Technical amendments.
- Sec. 705. Formal strategy relating to children separated from parents and guardians as a result of zero tolerance policy.
- Sec. 706. Reporting relating to children separated from parents and guardians as a result of zero tolerance policy.
- Sec. 707. Technical correction.
- Sec. 708. Savings clause.

1 **TITLE I—STRENGTHENING THE**  
2 **NATIONAL HEALTH SECURITY**  
3 **STRATEGY**

4 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

5 Section 2802 of the Public Health Service Act (42  
6 U.S.C. 300hh–1) is amended—

7 (1) in subsection (a)—

8 (A) in paragraph (1)—

9 (i) by striking “2014” and inserting  
10 “2018”; and

1 (ii) by striking the second sentence  
2 and inserting the following: “Such Na-  
3 tional Health Security Strategy shall de-  
4 scribe potential emergency health security  
5 threats and identify the process for achiev-  
6 ing the preparedness goals described in  
7 subsection (b) to be prepared to identify  
8 and respond to such threats and shall be  
9 consistent with the national preparedness  
10 goal (as described in section 504(a)(19) of  
11 the Homeland Security Act of 2002), the  
12 National Incident Management System (as  
13 defined in section 501(7) of such Act), and  
14 the National Response Plan developed pur-  
15 suant to section 504 of such Act, or any  
16 successor plan.”;

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

23 (C) in paragraph (3)—

24 (i) by striking “2009” and inserting  
25 “2022”;

1 (ii) by inserting “(including gaps in  
2 the environmental health and animal  
3 health workforces, as applicable), describ-  
4 ing the status of such workforce” after  
5 “gaps in such workforce”;

6 (iii) by striking “and identifying strat-  
7 egies” and inserting “identifying strate-  
8 gies”; and

9 (iv) by inserting before the period at  
10 the end “, and identifying current capabili-  
11 ties to meet the requirements of section  
12 2803”; and

13 (2) in subsection (b)—

14 (A) in paragraph (2)—

15 (i) in subparagraph (A), by striking  
16 “and investigation” and inserting “inves-  
17 tigation, and related information tech-  
18 nology activities”;

19 (ii) in subparagraph (B), by striking  
20 “and decontamination” and inserting “de-  
21 contamination, relevant health care serv-  
22 ices and supplies, and transportation and  
23 disposal of medical waste”; and

24 (iii) by adding at the end the fol-  
25 lowing:

1 “(E) Response to environmental hazards.”;

2 (B) in paragraph (3)—

3 (i) in the matter preceding subpara-  
4 graph (A), by striking “including mental  
5 health” and inserting “including phar-  
6 macies, mental health facilities,”; and

7 (ii) in subparagraph (F), by inserting  
8 “or exposures to agents that could cause a  
9 public health emergency” before the pe-  
10 riod;

11 (C) in paragraph (5), by inserting “and  
12 other applicable compacts” after “Compact”;  
13 and

14 (D) by adding at the end the following:

15 “(9) ZOOONOTIC DISEASE, FOOD, AND AGRI-  
16 CULTURE.—Improving coordination among Federal,  
17 State, local, tribal, and territorial entities (including  
18 through consultation with the Secretary of Agri-  
19 culture) to prevent, detect, and respond to outbreaks  
20 of plant or animal disease (including zoonotic dis-  
21 ease) that could compromise national security result-  
22 ing from a deliberate attack, a naturally occurring  
23 threat, the intentional adulteration of food, or other  
24 public health threats, taking into account inter-  
25 actions between animal health, human health, and

1 animals’ and humans’ shared environment as di-  
2 rectly related to public health emergency prepared-  
3 ness and response capabilities, as applicable.

4 “(10) GLOBAL HEALTH SECURITY.—Assessing  
5 current or potential health security threats from  
6 abroad to inform domestic public health prepared-  
7 ness and response capabilities.”.

8 **TITLE II—IMPROVING**  
9 **PREPAREDNESS AND RESPONSE**

10 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**  
11 **PREPAREDNESS AND RESPONSE.**

12 (a) EVALUATING MEASURABLE EVIDENCE-BASED  
13 BENCHMARKS AND OBJECTIVE STANDARDS.—Section  
14 319C–1 of the Public Health Service Act (42 U.S.C.  
15 247d–3a) is amended by inserting after subsection (j) the  
16 following:

17 “(k) EVALUATION.—

18 “(1) IN GENERAL.—Not later than 2 years  
19 after the date of enactment of the Pandemic and  
20 All-Hazards Preparedness and Advancing Innovation  
21 Act of 2018 and every 2 years thereafter, the Sec-  
22 retary shall conduct an evaluation of the evidence-  
23 based benchmarks and objective standards required  
24 under subsection (g). Such evaluation shall be sub-  
25 mitted to the congressional committees of jurisdic-

1           tion together with the National Health Security  
2           Strategy under section 2802, at such time as such  
3           strategy is submitted.

4           “(2) CONTENT.—The evaluation under this  
5           paragraph shall include—

6                   “(A) a review of evidence-based bench-  
7                   marks and objective standards, and associated  
8                   metrics and targets;

9                   “(B) a discussion of changes to any evi-  
10                  dence-based benchmarks and objective stand-  
11                  ards, and the effect of such changes on the abil-  
12                  ity to track whether entities are meeting or  
13                  making progress toward the goals under this  
14                  section and, to the extent practicable, the appli-  
15                  cable goals of the National Health Security  
16                  Strategy under section 2802;

17                  “(C) a description of amounts received by  
18                  eligible entities described in subsection (b) and  
19                  section 319C–2(b), and amounts received by  
20                  subrecipients and the effect of such funding on  
21                  meeting evidence-based benchmarks and objec-  
22                  tive standards; and

23                  “(D) recommendations, as applicable and  
24                  appropriate, to improve evidence-based bench-  
25                  marks and objective standards to more accu-

1           rately assess the ability of entities receiving  
2           awards under this section to better achieve the  
3           goals under this section and section 2802.”.

4           (b) EVALUATING THE PARTNERSHIP FOR STATE AND  
5 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–  
6 2(i)(1) of the Public Health Service Act (42 U.S.C. 247–  
7 3b(i)(1)) is amended by striking “section 319C–1(g), (i),  
8 and (j)” and inserting “section 319C–1(g), (i), (j), and  
9 (k)”.

10 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**  
11 **SPONSE PROGRAMS.**

12           (a) COOPERATIVE AGREEMENT APPLICATIONS FOR  
13 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-  
14 RITY.—Section 319C–1 of the Public Health Service Act  
15 (42 U.S.C. 247d–3a) is amended—

16           (1) in subsection (a), by inserting “, acting  
17 through the Director of the Centers for Disease  
18 Control and Prevention,” after “the Secretary”; and

19           (2) in subsection (b)(2)(A)—

20           (A) in clause (vi), by inserting “, including  
21 public health agencies with specific expertise  
22 that may be relevant to public health security,  
23 such as environmental health agencies,” after  
24 “stakeholders”;

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

3 (C) by inserting after clause (vi) the fol-  
4 lowing:

5 “(vii) a description of how, as applica-  
6 ble, such entity may integrate information  
7 to account for individuals with behavioral  
8 health needs following a public health  
9 emergency;”;

10 (D) in clause (ix), as so redesignated, by  
11 striking “; and” and inserting a semicolon;

12 (E) in clause (x), as so redesignated, by in-  
13 serting “and” after the semicolon; and

14 (F) by adding at the end the following:

15 “(xi) a description of how the entity  
16 will partner with health care facilities, in-  
17 cluding hospitals and nursing homes and  
18 other long-term care facilities, to promote  
19 and improve public health preparedness  
20 and response; and

21 “(xii) a description of how, as appro-  
22 priate and practicable, the entity will in-  
23 clude critical infrastructure partners, such  
24 as utility companies within the entity’s ju-  
25 risdiction, in planning pursuant to this



1           subparagraph to help ensure that critical  
2           infrastructure will remain functioning dur-  
3           ing, or return to function as soon as prac-  
4           ticable after, a public health emergency.”.

5           (b) EXCEPTION RELATING TO APPLICATION OF CER-  
6 TAIN REQUIREMENTS.—Section 319C–1(g) of the Public  
7 Health Service Act (42 U.S.C. 247d–3a(g)) is amended—

8           (1) in paragraph (5)—

9           (A) by striking “Beginning with fiscal year  
10           2009” and inserting “Beginning with fiscal  
11           year 2019”;

12           (B) by striking “for the immediately pre-  
13           ceding fiscal year” and inserting “for either of  
14           the two immediately preceding fiscal years”;  
15           and

16           (C) by striking “2008” and inserting  
17           “2019”; and

18           (2) by amending subparagraph (A) of para-  
19           graph (6) to read as follows:

20           “(A) IN GENERAL.—The amounts de-  
21           scribed in this paragraph are the following  
22           amounts that are payable to an entity for ac-  
23           tivities described in section 319C–1 or 319C–2:

24           “(i) For one (but not both) of the  
25           first two fiscal years immediately following

1 a fiscal year in which an entity experienced  
2 a failure described in subparagraph (A) or  
3 (B) of paragraph (5) by the entity, an  
4 amount equal to 10 percent of the amount  
5 the entity was eligible to receive for the re-  
6 spective fiscal year.

7 “(ii) For one (but not both) of the  
8 first two fiscal years immediately following  
9 the third consecutive fiscal year in which  
10 an entity experienced such a failure, in lieu  
11 of applying clause (i), an amount equal to  
12 15 percent of the amount the entity was el-  
13 igible to receive for the respective fiscal  
14 year.”.

15 (b) PARTNERSHIP FOR STATE AND REGIONAL HOS-  
16 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—  
17 Section 319C–2 of the Public Health Service Act (42  
18 U.S.C. 247d–3b) is amended—

19 (1) in subsection (a)—

20 (A) by inserting “, acting through the As-  
21 sistant Secretary for Preparedness and Re-  
22 sponse,” after “The Secretary”; and

23 (B) by striking “preparedness for public  
24 health emergencies” and inserting “prepared-

1           ness for, and response to, public health emer-  
2           gencies in accordance with subsection (c)”;

3           (2) in subsection (b)(1)(A)—

4                 (A) by striking “partnership consisting of”  
5                 and inserting “coalition that includes”;

6                 (B) in clause (ii), by striking “; and” and  
7                 inserting a semicolon; and

8                 (C) by adding at the end the following:

9                     “(iv) one or more emergency medical serv-  
10                    ice organizations or emergency management or-  
11                    ganizations; and”;

12           (3) in subsection (d)—

13                 (A) in paragraph (1)(B), by striking “part-  
14                 nership” each place it appears and inserting  
15                 “coalition”; and

16                 (B) in paragraph (2)(C), by striking “med-  
17                 ical preparedness” and inserting “preparedness  
18                 and response”;

19           (4) in subsection (f), by striking “partnership”  
20           and inserting “coalition”;

21           (5) in subsection (g)(2)—

22                 (A) by striking “Partnerships” and insert-  
23                 ing “Coalitions”;

24                 (B) by striking “partnerships” and insert-  
25                 ing “coalitions”; and

1 (C) by inserting “and response” after  
2 “preparedness”; and

3 (6) in subsection (i)(1)—

4 (A) by striking “An entity” and inserting  
5 “A coalition”; and

6 (B) by striking “such partnership” and in-  
7 serting “such coalition”.

8 (c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-  
9 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) of  
10 the Public Health Service Act (42 U.S.C. 247d–  
11 3a(h)(1)(A)) is amended by striking “\$641,900,000 for  
12 fiscal year 2014” and all that follows through the period  
13 at the end and inserting “\$685,000,000 for each of fiscal  
14 years 2019 through 2023 for awards pursuant to para-  
15 graph (3) (subject to the authority of the Secretary to  
16 make awards pursuant to paragraphs (4) and (5)).”.

17 (d) PARTNERSHIP FOR STATE AND REGIONAL HOS-  
18 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-  
19 TIONS.—Section 319C–2(j) of the Public Health Service  
20 Act (42 U.S.C. 247d–3b(j)) is amended—

21 (1) by amending paragraph (1) to read as fol-  
22 lows:

23 “(1) IN GENERAL.—

24 “(A) AUTHORIZATION OF APPROPRIA-  
25 TIONS.—For purposes of carrying out this sec-

1           tion and section 319C–3, in accordance with  
2           subparagraph (B), there is authorized to be ap-  
3           propriated \$385,000,000 for each of fiscal years  
4           2019 through 2023.

5           “(B) RESERVATION OF AMOUNTS FOR RE-  
6           GIONAL SYSTEMS.—

7                   “(i) IN GENERAL.—Subject to clause  
8                   (ii), of the amount appropriated under sub-  
9                   paragraph (A) for a fiscal year, the Sec-  
10                  retary may reserve up to 5 percent for the  
11                  purpose of carrying out section 319C–3.

12                   “(ii) RESERVATION CONTINGENT ON  
13                   CONTINUED APPROPRIATIONS FOR THIS  
14                   SECTION.—If for fiscal year 2019 or a sub-  
15                   sequent fiscal year, the amount appro-  
16                   priated under subparagraph (A) is such  
17                   that, after application of clause (i), the  
18                   amount remaining for the purpose of car-  
19                   rying out this section would be less than  
20                   the amount available for such purpose for  
21                   the previous fiscal year, the amount that  
22                   may be reserved under clause (i) shall be  
23                   reduced such that the amount remaining  
24                   for the purpose of carrying out this section

1 is not less than the amount available for  
2 such purpose for the previous fiscal year.

3 “(iii) SUNSET.—The authority to re-  
4 serve amounts under clause (i) shall expire  
5 on September 30, 2023.”;

6 (2) in paragraph (2), by striking “paragraph  
7 (1) for a fiscal year” and inserting “paragraph  
8 (1)(A) for a fiscal year and not reserved for the pur-  
9 pose described in paragraph (1)(B)(i)”; and

10 (3) in paragraph (3)(A), by striking “paragraph  
11 (1) and not reserved under paragraph (2)” and in-  
12 serting “paragraph (1)(A) and not reserved under  
13 paragraph (1)(B)(i) or (2)”.

14 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**  
15 **PAREDNESS AND RESPONSE SYSTEMS.**

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

19 **“SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE**  
20 **EMERGENCY PREPAREDNESS AND RESPONSE**  
21 **SYSTEMS.**

22 “(a) PURPOSE.—It is the purpose of this section to  
23 identify and provide guidelines for regional systems of hos-  
24 pitals, health care facilities, and other public and private  
25 sector entities, with varying levels of capability to treat

1 patients and increase medical surge capacity during, in ad-  
2 vance of, and immediately following a public health emer-  
3 gency, including threats posed by one or more chemical,  
4 biological, radiological, or nuclear agents, including emerg-  
5 ing infectious diseases.

6 “(b) GUIDELINES.—The Assistant Secretary for Pre-  
7 paredness and Response, in consultation with the Director  
8 of the Centers for Disease Control and Prevention, the Ad-  
9 ministrator of the Centers for Medicare & Medicaid Serv-  
10 ices, the Administrator of the Health Resources and Serv-  
11 ices Administration, the Commissioner of Food and  
12 Drugs, the Assistant Secretary for Mental Health and  
13 Substance Use, the Assistant Secretary of Labor for Occu-  
14 pational Safety and Health, the Secretary of Veterans Af-  
15 fairs, the heads of such other Federal agencies as the Sec-  
16 retary determines to be appropriate, and State, local, trib-  
17 al, and territorial public health officials, shall, not later  
18 than 2 years after the date of enactment of this section—

19 “(1) identify and develop a set of guidelines re-  
20 lating to practices and protocols for all-hazards pub-  
21 lic health emergency preparedness and response for  
22 hospitals and health care facilities to provide appro-  
23 priate patient care during, in advance of, or imme-  
24 diately following, a public health emergency, result-  
25 ing from one or more chemical, biological, radio-

1       logical, or nuclear agents, including emerging infec-  
2       tious diseases (which may include existing practices,  
3       such as trauma care and medical surge capacity and  
4       capabilities), with respect to—

5               “(A) a regional approach to identifying  
6       hospitals and health care facilities based on  
7       varying capabilities and capacity to treat pa-  
8       tients affected by such emergency, including—

9               “(i) the manner in which the system  
10       will coordinate with and integrate the part-  
11       nerships and health care coalitions estab-  
12       lished under section 319C–2(b); and

13              “(ii) informing and educating appro-  
14       priate first responders and health care sup-  
15       ply chain partners of the regional emer-  
16       gency preparedness and response capabili-  
17       ties and medical surge capacity of such  
18       hospitals and health care facilities in the  
19       community;

20              “(B) physical and technological infrastruc-  
21       ture, laboratory capacity, staffing, blood supply,  
22       and other supply chain needs, taking into ac-  
23       count resiliency, geographic considerations, and  
24       rural considerations;



1           “(C) protocols or best practices for the  
2           safety and personal protection of workers who  
3           handle human remains and health care workers  
4           (including with respect to protective equipment  
5           and supplies, waste management processes, and  
6           decontamination), sharing of specialized experi-  
7           ence among the health care workforce, behav-  
8           ioral health, psychological resilience, and train-  
9           ing of the workforce, as applicable;

10           “(D) in a manner that allows for disease  
11           containment (within the meaning of section  
12           2802(b)(2)(B)), coordinated medical triage,  
13           treatment, and transportation of patients, based  
14           on patient medical need (including patients in  
15           rural areas), to the appropriate hospitals or  
16           health care facilities within the regional system  
17           or, as applicable and appropriate, between sys-  
18           tems in different States or regions; and

19           “(E) the needs of children and other at-  
20           risk individuals;

21           “(2) make such guidelines available on the  
22           internet website of the Department of Health and  
23           Human Services in a manner that does not com-  
24           promise national security; and

1           “(3) update such guidelines as appropriate, in-  
2           cluding based on input received pursuant to sub-  
3           sections (c) and (e) and information resulting from  
4           applicable reports required under the Pandemic and  
5           All-Hazards Preparedness and Advancing Innovation  
6           Act of 2018 (including any amendments made by  
7           such Act), to address new and emerging public  
8           health threats.

9           “(c) CONSIDERATIONS.—In identifying, developing,  
10          and updating guidelines under subsection (b), the Assist-  
11          ant Secretary for Preparedness and Response shall—

12           “(1) include input from hospitals and health  
13           care facilities (including health care coalitions under  
14           section 319C–2), State, local, tribal, and territorial  
15           public health departments, and health care or sub-  
16           ject matter experts (including experts with relevant  
17           expertise in chemical, biological, radiological, or nu-  
18           clear threats, including emerging infectious dis-  
19           eases), as the Assistant Secretary determines appro-  
20           priate, to meet the goals under section 2802(b)(3);

21           “(2) consult and engage with appropriate  
22           health care providers and professionals, including  
23           physicians, nurses, first responders, health care fa-  
24           cilities (including hospitals, primary care clinics,  
25           community health centers, mental health facilities,

1 ambulatory care facilities, and dental health facili-  
2 ties), pharmacies, emergency medical providers,  
3 trauma care providers, environmental health agen-  
4 cies, public health laboratories, poison control cen-  
5 ters, blood banks, and other experts that the Assist-  
6 ant Secretary determines appropriate, to meet the  
7 goals under section 2802(b)(3);

8 “(3) consider feedback related to financial im-  
9 plications for hospitals, health care facilities, public  
10 health agencies, laboratories, blood banks, and other  
11 entities engaged in regional preparedness planning  
12 to implement and follow such guidelines, as applica-  
13 ble; and

14 “(4) consider financial requirements and poten-  
15 tial incentives for entities to prepare for, and re-  
16 spond to, public health emergencies as part of the  
17 regional health care emergency preparedness and re-  
18 sponse system.

19 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-  
20 retary for Preparedness and Response, in consultation  
21 with the Director of the Centers for Disease Control and  
22 Prevention and the Assistant Secretary of Labor for Occu-  
23 pational Safety and Health, may provide technical assist-  
24 ance and consultation toward meeting the guidelines de-  
25 scribed in subsection (b).

1 “(e) DEMONSTRATION PROJECT FOR REGIONAL  
2 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-  
3 TEMS.—

4 “(1) IN GENERAL.—The Assistant Secretary for  
5 Preparedness and Response may establish a dem-  
6 onstration project pursuant to the development and  
7 implementation of guidelines under subsection (b) to  
8 award grants to improve medical surge capacity for  
9 all hazards, build and integrate regional medical re-  
10 sponse capabilities, improve specialty care expertise  
11 for all-hazards response, and coordinate medical pre-  
12 paredness and response across State, local, tribal,  
13 territorial, and regional jurisdictions.

14 “(2) SUNSET.—The authority under this sub-  
15 section shall expire on September 30, 2023.”.

16 (b) GAO REPORT TO CONGRESS.—

17 (1) REPORT.—Not later than 3 years after the  
18 date of enactment of this Act, the Comptroller Gen-  
19 eral of the United States (referred to in this sub-  
20 section as the “Comptroller General”) shall submit  
21 to the Committee on Health, Education, Labor, and  
22 Pensions and the Committee on Finance of the Sen-  
23 ate and the Committee on Energy and Commerce  
24 and the Committee on Ways and Means of the  
25 House of Representatives, a report on the extent to

1       which hospitals and health care facilities have imple-  
2       mented the recommended guidelines under section  
3       319C–3(b) of the Public Health Service Act (as  
4       added by subsection (a)), including an analysis and  
5       evaluation of any challenges hospitals or health care  
6       facilities experienced in implementing such guide-  
7       lines.

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

10               (A) data on the preparedness and response  
11               capabilities that have been informed by the  
12               guidelines under section 319C–3(b) of the Pub-  
13               lic Health Service Act to improve regional emer-  
14               gency health care preparedness and response  
15               capability, including hospital and health care  
16               facility capacity and medical surge capabilities  
17               to prepare for, and respond to, public health  
18               emergencies; and

19               (B) recommendations to reduce gaps in in-  
20               centives for regional health partners, including  
21               hospitals and health care facilities, to improve  
22               capacity and medical surge capabilities to pre-  
23               pare for, and respond to, public health emer-  
24               gencies, consistent with subsection (a), which  
25               may include consideration of facilities partici-

1           pating in programs under section 319C–2 of  
2           the Public Health Service Act (42 U.S.C.  
3           247d–3b) or in programs under the Centers for  
4           Medicare & Medicaid Services (including inno-  
5           vative health care delivery and payment mod-  
6           els), and input from private sector financial in-  
7           stitutions.

8           (3) CONSULTATION.—In carrying out para-  
9           graphs (1) and (2), the Comptroller General shall  
10          consult with the heads of appropriate Federal agen-  
11          cies, including—

12                   (A) the Assistant Secretary for Prepared-  
13                   ness and Response;

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

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

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

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

22                   (F) the Secretary of Veterans Affairs.

23          (c) ANNUAL REPORTS.—Section 319C–2(i)(1) of the  
24          Public Health Service Act (42 U.S.C. 247d–3b(i)(1)) is  
25          amended by inserting after the first sentence the following

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

5 (d) NATIONAL HEALTH SECURITY STRATEGY INCOR-  
6 PORATION OF REGIONALIZED EMERGENCY PREPARED-  
7 NESS AND RESPONSE.—Subparagraph (G) of section  
8 2802(b)(3) of the Public Health Service Act (42 U.S.C.  
9 300hh–1(b)(3)) is amended to read as follows:

10 “(G) Optimizing a coordinated and flexible  
11 approach to the emergency response and med-  
12 ical surge capacity of hospitals, other health  
13 care facilities, critical care, trauma care (which  
14 may include trauma centers), and emergency  
15 medical systems.”.

16 (e) IMPROVING STATE AND LOCAL PUBLIC HEALTH  
17 SECURITY.—

18 (1) STATE AND LOCAL SECURITY.—Section  
19 319C–1(e) of the Public Health Service Act (42  
20 U.S.C. 247d–3a(e)) is amended by striking “, and  
21 local emergency plans.” and inserting “, local emer-  
22 gency plans, and any regional health care emergency  
23 preparedness and response system established pursu-  
24 ant to the applicable guidelines under section 319C–  
25 3.”.

1 (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)  
2 of the Public Health Service Act (42 U.S.C. 247d-  
3 3b(d)(1)(A)) is amended—

4 (A) in clause (i), by striking “; and” and  
5 inserting “;”;

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

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

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

12 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
13 **TRAUMA READINESS.**

14 Title XII of the Public Health Service Act (42 U.S.C.  
15 300d et seq.) is amended by adding at the end the fol-  
16 lowing new part:

17 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**  
18 **FOR TRAUMA READINESS GRANT PROGRAM**

19 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
20 **TRAUMA READINESS GRANT PROGRAM.**

21 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-  
22 GRAM.—

23 “(1) IN GENERAL.—The Secretary, acting  
24 through the Assistant Secretary for Preparedness  
25 and Response and in consultation with the Secretary



1 of Defense, shall award grants to not more than 20  
2 eligible high acuity trauma centers to enable military  
3 trauma teams to provide, on a full-time basis, trauma  
4 care and related acute care at such trauma centers.  
5

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

9 “(A) shall be for a period of at least 3  
10 years and not more than 5 years (and may be  
11 renewed at the end of such period); and

12 “(B) shall be in an amount that does not  
13 exceed \$1,000,000 per year.

14 “(3) AVAILABILITY OF FUNDS.—Notwith-  
15 standing section 1552 of title 31, United States  
16 Code, or any other provision of law, funds available  
17 to the Secretary for obligation for a grant under this  
18 subsection shall remain available for expenditure for  
19 100 days after the last day of the performance pe-  
20 riod of such grant.

21 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-  
22 MENT PROGRAM.—

23 “(1) IN GENERAL.—The Secretary, acting  
24 through the Assistant Secretary for Preparedness  
25 and Response and in consultation with the Secretary

1 of Defense, shall award grants to eligible trauma  
2 centers to enable military trauma care providers to  
3 provide trauma care and related acute care at such  
4 trauma centers.

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

8 “(A) shall be for a period of at least 1 year  
9 and not more than 3 years (and may be re-  
10 newed at the end of such period); and

11 “(B) shall be in an amount that does not  
12 exceed, in a year—

13 “(i) \$100,000 for each military trau-  
14 ma care provider that is a physician at  
15 such eligible trauma center; and

16 “(ii) \$50,000 for each other military  
17 trauma care provider at such eligible trau-  
18 ma center.

19 “(c) GRANT REQUIREMENTS.—

20 “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-  
21 GENCIES.—As a condition of receipt of a grant  
22 under this section, a grant recipient shall agree to  
23 allow military trauma care providers providing care  
24 pursuant to such grant to—

1           “(A) be deployed by the Secretary of De-  
2           fense for military operations, for training, or  
3           for response to a mass casualty incident; and

4           “(B) be deployed by the Secretary of De-  
5           fense, in consultation with the Secretary of  
6           Health and Human Services, for response to a  
7           public health emergency pursuant to section  
8           319.

9           “(2) USE OF FUNDS.—Grants awarded under  
10          this section to an eligible trauma center may be used  
11          to train and incorporate military trauma care pro-  
12          viders into such trauma center, including incorpora-  
13          tion into operational exercises and training drills re-  
14          lated to public health emergencies, expenditures for  
15          malpractice insurance, office space, information  
16          technology, specialty education and supervision,  
17          trauma programs, research, and applicable license  
18          fees for such military trauma care providers.

19          “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
20          tion shall be construed to affect any other provision of law  
21          that preempts State licensing requirements for health care  
22          professionals, including with respect to military trauma  
23          care providers.

24          “(e) REPORTING REQUIREMENTS.—

1           “(1) REPORT TO THE SECRETARY AND THE  
2           SECRETARY OF DEFENSE.—Each eligible trauma  
3           center or eligible high acuity trauma center awarded  
4           a grant under subsection (a) or (b) for a year shall  
5           submit to the Secretary and the Secretary of De-  
6           fense a report for such year that includes informa-  
7           tion on—

8                   “(A) the number and types of trauma  
9                   cases managed by military trauma teams or  
10                  military trauma care providers pursuant to such  
11                  grant during such year;

12                   “(B) the ability to maintain the integration  
13                  of the military trauma providers or teams of  
14                  providers as part of the trauma center, includ-  
15                  ing the financial effect of such grant on the  
16                  trauma center;

17                   “(C) the educational effect on resident  
18                  trainees in centers where military trauma teams  
19                  are assigned;

20                   “(D) any research conducted during such  
21                  year supported by such grant; and

22                   “(E) any other information required by the  
23                  Secretaries for the purpose of evaluating the ef-  
24                  fect of such grant.

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

8                   “(A) maintaining military trauma care  
9                   providers’ readiness and ability to respond to  
10                  and treat battlefield injuries;

11                  “(B) providing health care to civilian trau-  
12                  ma patients in urban and rural settings;

13                  “(C) the capability of trauma centers and  
14                  military trauma care providers to increase med-  
15                  ical surge capacity, including as a result of a  
16                  large scale event;

17                  “(D) the ability of grant recipients to  
18                  maintain the integration of the military trauma  
19                  providers or teams of providers as part of the  
20                  trauma center;

21                  “(E) efforts to incorporate military trauma  
22                  care providers into operational exercises and  
23                  training and drills for public health emer-  
24                  gencies; and

1           “(F) the capability of military trauma care  
2 providers to participate as part of a medical re-  
3 sponse during or in advance of a public health  
4 emergency, as determined by the Secretary, or  
5 a mass casualty incident.

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

7           “(1) ELIGIBLE TRAUMA CENTER.—The term  
8 ‘eligible trauma center’ means a Level I, II, or III  
9 trauma center that satisfies each of the following:

10           “(A) Such trauma center has an agree-  
11 ment with the Secretary of Defense to enable  
12 military trauma care providers to provide trau-  
13 ma care and related acute care at such trauma  
14 center.

15           “(B) Such trauma center utilizes a risk-ad-  
16 justed benchmarking system and metrics to  
17 measure performance, quality, and patient out-  
18 comes.

19           “(C) Such trauma center demonstrates a  
20 need for integrated military trauma care pro-  
21 viders to maintain or improve the trauma clin-  
22 ical capability of such trauma center.

23           “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-  
24 TER.—The term ‘eligible high acuity trauma center’

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

3 “(A) Such trauma center has an agree-  
4 ment with the Secretary of Defense to enable  
5 military trauma teams to provide trauma care  
6 and related acute care at such trauma center.

7 “(B) At least 20 percent of patients treat-  
8 ed at such trauma center in the most recent 3-  
9 month period for which data are available are  
10 treated for a major trauma at such trauma cen-  
11 ter.

12 “(C) Such trauma center utilizes a risk-ad-  
13 justed benchmarking system and metrics to  
14 measure performance, quality, and patient out-  
15 comes.

16 “(D) Such trauma center is an academic  
17 training center—

18 “(i) affiliated with a medical school;

19 “(ii) that maintains residency pro-  
20 grams and fellowships in critical trauma  
21 specialties and subspecialties, and provides  
22 education and supervision of military trau-  
23 ma team members according to those spe-  
24 cialties and subspecialties; and

1                   “(iii) that undertakes research in the  
2                   prevention and treatment of traumatic in-  
3                   jury.

4                   “(E) Such trauma center serves as a med-  
5                   ical and public health preparedness and re-  
6                   sponse leader for its community, such as by  
7                   participating in a partnership for State and re-  
8                   gional hospital preparedness established under  
9                   section 319C-2 or 319C-3.

10                  “(3) MAJOR TRAUMA.—The term ‘major trau-  
11                  ma’ means an injury that is greater than or equal  
12                  to 15 on the injury severity score.

13                  “(4) MILITARY TRAUMA TEAM.—The term  
14                  ‘military trauma team’ means a complete military  
15                  trauma team consisting of military trauma care pro-  
16                  viders.

17                  “(5) MILITARY TRAUMA CARE PROVIDER.—The  
18                  term ‘military trauma care provider’ means a mem-  
19                  ber of the Armed Forces who furnishes emergency,  
20                  critical care, and other trauma acute care services  
21                  (including a physician, surgeon, physician assistant,  
22                  nurse, nurse practitioner, respiratory therapist,  
23                  flight paramedic, combat medic, or enlisted medical  
24                  technician), or other military trauma care provider  
25                  as the Secretary determines appropriate.



1       “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there are authorized to be appro-  
3 priated \$15,000,000 for each of fiscal years 2019 through  
4 2023, of which—

5           “(1)  $\frac{2}{3}$  of the amount made available each fis-  
6 cal year shall be made available for grants under  
7 subsection (a); and

8           “(2)  $\frac{1}{3}$  of the amount made available each fis-  
9 cal year shall be made available for grants under  
10 subsection (b).”.

11 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**  
12 **UATIONAL AWARENESS AND BIOSURVEIL-**  
13 **LANCE CAPABILITIES.**

14       (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE  
15 CAPABILITIES.—Section 319D of the Public Health Serv-  
16 ice Act (42 U.S.C. 247d–4) is amended—

17           (1) in the section heading, by striking “**REVI-**  
18 **TALIZING**” and inserting “**FACILITIES AND CA-**  
19 **PACITIES OF**”;

20           (2) in subsection (a)—

21           (A) in the subsection heading, by striking  
22 “**FACILITIES; CAPACITIES**” and inserting “**IN**  
23 **GENERAL**”;

1 (B) in paragraph (1), by striking “and im-  
2 proved” and inserting “, improved, and appro-  
3 priately maintained”;

4 (C) in paragraph (3), in the matter pre-  
5 ceeding subparagraph (A), by striking “expand,  
6 enhance, and improve” and inserting “expand,  
7 improve, enhance, and appropriately maintain”;  
8 and

9 (D) by adding at the end the following:

10 “(4) STUDY OF RESOURCES FOR FACILITIES  
11 AND CAPACITIES.—Not later than June 1, 2022, the  
12 Comptroller General of the United States shall con-  
13 duct a study on Federal spending in fiscal years  
14 2013 through 2018 for activities authorized under  
15 this subsection. Such study shall include a review  
16 and assessment of obligations and expenditures di-  
17 rectly related to each activity under paragraphs (2)  
18 and (3), including a specific accounting of, and de-  
19 lineation between, obligations and expenditures in-  
20 curred for the construction, renovation, equipping,  
21 and security upgrades of facilities and associated  
22 contracts under this subsection, and the obligations  
23 and expenditures incurred to establish and improve  
24 the situational awareness and biosurveillance net-  
25 work under subsection (b), and shall identify the

1 agency or agencies incurring such obligations and  
2 expenditures.”;

3 (3) in subsection (b)—

4 (A) in the subsection heading, by striking  
5 “NATIONAL” and inserting “ESTABLISHMENT  
6 OF SYSTEMS OF PUBLIC HEALTH”;

7 (B) in paragraph (1)(B), by inserting “im-  
8 munization information systems,” after “cen-  
9 ters,”; and

10 (C) in paragraph (2)—

11 (i) by inserting “develop a plan to,  
12 and” after “The Secretary shall”; and

13 (ii) by inserting “and in a form read-  
14 ily usable for analytical approaches” after  
15 “in a secure manner”; and

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

18 “(3) STANDARDS.—

19 “(A) IN GENERAL.—Not later than 1 year  
20 after the date of the enactment of the Pan-  
21 demic and All-Hazards Preparedness and Ad-  
22 vancing Innovation Act of 2018, the Secretary,  
23 in cooperation with health care providers, State,  
24 local, tribal, and territorial public health offi-  
25 cials, and relevant Federal agencies (including

1 the Office of the National Coordinator for  
2 Health Information Technology and the Na-  
3 tional Institute of Standards and Technology),  
4 shall, as necessary, adopt technical and report-  
5 ing standards, including standards for inter-  
6 operability as defined by section 3000, for net-  
7 works under paragraph (1) and update such  
8 standards as necessary. Such standards shall be  
9 made available on the internet website of the  
10 Department of Health and Human Services, in  
11 a manner that does not compromise national se-  
12 curity.

13 “(B) DEFERENCE TO STANDARDS DEVEL-  
14 OPMENT ORGANIZATIONS.—In adopting and im-  
15 plementing standards under this subsection and  
16 subsection (c), the Secretary shall give def-  
17 erence to standards published by standards de-  
18 velopment organizations and voluntary con-  
19 sensus-based standards entities.”;

20 (4) in subsection (c)—

21 (A) in paragraph (1)—

22 (i) by striking “Not later than 2 years  
23 after the date of enactment of the Pan-  
24 demic and All-Hazards Preparedness Re-

1 authorization Act of 2013, the Secretary”  
2 and inserting “The Secretary”;

3 (ii) by inserting “, and improve as ap-  
4 plicable and appropriate,” after “shall es-  
5 tablish”;

6 (iii) by striking “of rapid” and insert-  
7 ing “of, rapid”; and

8 (iv) by striking “such connectivity”  
9 and inserting “such interoperability”;

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

12 “(2) COORDINATION AND CONSULTATION.—In  
13 establishing and improving the network under para-  
14 graph (1) the Secretary shall—

15 “(A) facilitate coordination among agencies  
16 within the Department of Health and Human  
17 Services that provide, or have the potential to  
18 provide, information and data to, and analyses  
19 for, the situational awareness and biosurveil-  
20 lance network under paragraph (1), including  
21 coordination among relevant agencies related to  
22 health care services, the facilitation of health  
23 information exchange (including the Office of  
24 the National Coordinator for Health Informa-

1           tion Technology), and public health emergency  
2           preparedness and response; and

3           “(B) consult with the Secretary of Agri-  
4           culture, the Secretary of Commerce (and the  
5           Director of the National Institute of Standards  
6           and Technology), the Secretary of Defense, the  
7           Secretary of Homeland Security, the Secretary  
8           of Veterans Affairs, and the heads of other  
9           Federal agencies, as the Secretary determines  
10          appropriate.”;

11          (C) in paragraph (3)—

12           (i) by redesignating subparagraphs  
13           (A) through (E) as clauses (i) through (v),  
14           respectively, and adjusting the margins ac-  
15           cordingly;

16           (ii) in clause (iv), as so redesign-  
17           ated—

18           (I) by inserting “immunization  
19           information systems,” after “poison  
20           control,”; and

21           (II) by striking “and clinical lab-  
22           oratories” and inserting “, clinical  
23           laboratories, and public environmental  
24           health agencies”;

1 (iii) by striking “The network” and  
2 inserting the following:

3 “(A) IN GENERAL.—The network”; and

4 (iv) by adding at the end the fol-  
5 lowing:

6 “(B) REVIEW.—Not later than 2 years  
7 after the date of the enactment of the Pan-  
8 demic and All-Hazards Preparedness and Ad-  
9 vancing Innovation Act of 2018 and every 6  
10 years thereafter, the Secretary shall conduct a  
11 review of the elements described in subpara-  
12 graph (A). Such review shall include a discus-  
13 sion of the addition of any elements pursuant to  
14 clause (v), including elements added to advanc-  
15 ing new technologies, and identify any chal-  
16 lenges in the incorporation of elements under  
17 subparagraph (A). The Secretary shall provide  
18 such review to the congressional committees of  
19 jurisdiction.”;

20 (D) in paragraph (5)—

21 (i) by redesignating subparagraphs  
22 (A) through (D) as clauses (i) through  
23 (iv), respectively, and adjusting the mar-  
24 gins accordingly;

1 (ii) by striking “In establishing” and  
2 inserting the following:

3 “(A) IN GENERAL.—In establishing”;

4 (iii) by adding at the end the fol-  
5 lowing:

6 “(B) PUBLIC MEETING.—

7 “(i) IN GENERAL.—Not later than  
8 180 days after the date of enactment of  
9 the Pandemic and All-Hazards Prepared-  
10 ness and Advancing Innovation Act of  
11 2018, the Secretary shall convene a public  
12 meeting for purposes of discussing and  
13 providing input on the potential goals,  
14 functions, and uses of the network de-  
15 scribed in paragraph (1) and incorporating  
16 the elements described in paragraph  
17 (3)(A).

18 “(ii) EXPERTS.—The public meeting  
19 shall include representatives of relevant  
20 Federal agencies (including representatives  
21 from the Office of the National Coordi-  
22 nator for Health Information Technology  
23 and the National Institute of Standards  
24 and Technology); State, local, tribal, and  
25 territorial public health officials; stake-



1 holders with expertise in biosurveillance  
2 and situational awareness; stakeholders  
3 with expertise in capabilities relevant to  
4 biosurveillance and situational awareness,  
5 such as experts in informatics and data  
6 analytics (including experts in prediction,  
7 modeling, or forecasting); and other rep-  
8 resentatives as the Secretary determines  
9 appropriate.

10 “(iii) TOPICS.—Such public meeting  
11 shall include a discussion of—

12 “(I) data elements, including  
13 minimal or essential data elements,  
14 that are voluntarily provided for such  
15 network, which may include elements  
16 from public health and public and pri-  
17 vate health care entities, to the extent  
18 practicable;

19 “(II) standards and implementa-  
20 tion specifications that may improve  
21 the collection, analysis, and interpre-  
22 tation of data during a public health  
23 emergency;

1 “(III) strategies to encourage the  
2 access, exchange, and use of informa-  
3 tion;

4 “(IV) considerations for State,  
5 local, tribal, and territorial capabilities  
6 and infrastructure related to data ex-  
7 change and interoperability;

8 “(V) privacy and security protec-  
9 tions provided at the Federal, State,  
10 local, tribal, and territorial levels, and  
11 by nongovernmental stakeholders; and

12 “(VI) opportunities for the incor-  
13 poration of innovative technologies to  
14 improve the network.”; and

15 (iv) in subparagraph (A), as so des-  
16 ignated by clause (ii)—

17 (I) in clause (i), as so redesign-  
18 nated—

19 (aa) by striking “as deter-  
20 mined” and inserting “as adopt-  
21 ed”; and

22 (bb) by inserting “and the  
23 National Institute of Standards  
24 and Technology” after “Office of

1 the National Coordinator for  
2 Health Information Technology”;

3 (II) in clause (iii), as so redesign-  
4 nated, by striking “; and” and insert-  
5 ing a semicolon;

6 (III) in clause (iv), as so redesign-  
7 nated, by striking the period and in-  
8 serting “; and”; and

9 (IV) by adding at the end the fol-  
10 lowing:

11 “(v) pilot test standards and imple-  
12 mentation specifications, consistent with  
13 the process described in section  
14 3002(b)(3)(C), which State, local, tribal,  
15 and territorial public health entities may  
16 utilize, on a voluntary basis, as a part of  
17 the network.”;

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

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

22 “(6) STRATEGY AND IMPLEMENTATION  
23 PLAN.—

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

1           demic and All-Hazards Preparedness and Ad-  
2           vancing Innovation Act of 2018, the Secretary  
3           shall submit to the congressional committees of  
4           jurisdiction a coordinated strategy and an ac-  
5           companying implementation plan that—

6                   “(i) is informed by the public meeting  
7                   under paragraph (5)(B);

8                   “(ii) includes a review and assessment  
9                   of existing capabilities of the network and  
10                  related infrastructure, including input pro-  
11                  vided by the public meeting under para-  
12                  graph (5)(B);

13                  “(iii) identifies and demonstrates the  
14                  measurable steps the Secretary will carry  
15                  out to—

16                          “(I) develop, implement, and  
17                          evaluate the network described in  
18                          paragraph (1), utilizing elements de-  
19                          scribed in paragraph (3)(A);

20                          “(II) modernize and enhance bio-  
21                          surveillance activities, including strat-  
22                          egies to include innovative tech-  
23                          nologies and analytical approaches  
24                          (including prediction and forecasting

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

3 “(III) improve information shar-  
4 ing, coordination, and communication  
5 among disparate biosurveillance sys-  
6 tems supported by the Department of  
7 Health and Human Services, includ-  
8 ing the identification of methods to  
9 improve accountability, better utilize  
10 resources and workforce capabilities,  
11 and incorporate innovative tech-  
12 nologies within and across agencies;  
13 and

14 “(IV) test and evaluate capabili-  
15 ties of the interoperable network of  
16 systems to improve situational aware-  
17 ness and biosurveillance capabilities;

18 “(iv) includes performance measures  
19 and the metrics by which performance  
20 measures will be assessed with respect to  
21 the measurable steps under clause (iii);  
22 and

23 “(v) establishes dates by which each  
24 measurable step under clause (iii) will be  
25 implemented.

1           “(B) ANNUAL BUDGET PLAN.—Not later  
2 than 2 years after the date of enactment of the  
3 Pandemic and All-Hazards Preparedness and  
4 Advancing Innovation Act of 2018 and on an  
5 annual basis thereafter, in accordance with the  
6 strategy and implementation plan under this  
7 paragraph, the Secretary shall, taking into ac-  
8 count recommendations provided by the Na-  
9 tional Biodefense Science Board, develop a  
10 budget plan based on the strategy and imple-  
11 mentation plan under this section. Such budget  
12 plan shall include—

13                   “(i) a summary of resources pre-  
14 viously expended to establish, improve, and  
15 utilize the nationwide public health situa-  
16 tional awareness and biosurveillance net-  
17 work under paragraph (1);

18                   “(ii) estimates of costs and resources  
19 needed to establish and improve the net-  
20 work under paragraph (1) according to the  
21 strategy and implementation plan under  
22 subparagraph (A);

23                   “(iii) the identification of gaps and in-  
24 efficiencies in nationwide public health sit-  
25 uational awareness and biosurveillance ca-

1 pabilities, resources, and authorities need-  
2 ed to address such gaps; and

3 “(iv) a strategy to minimize and ad-  
4 dress such gaps and improve inefficien-  
5 cies.”;

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

7 (i) in subparagraph (A), by inserting  
8 “(taking into account zoonotic disease, in-  
9 cluding gaps in scientific understanding of  
10 the interactions between human, animal,  
11 and environmental health)” after “human  
12 health”;

13 (ii) in subparagraph (B)—

14 (I) by inserting “and gaps in sur-  
15 veillance programs” after “surveil-  
16 lance programs”; and

17 (II) by striking “; and” and in-  
18 serting a semicolon;

19 (iii) in subparagraph (C)—

20 (I) by inserting “, animal health  
21 organizations related to zoonotic dis-  
22 ease,” after “health care entities”;  
23 and

24 (II) by striking the period and  
25 inserting “; and”; and

1 (iv) by adding at the end the fol-  
2 lowing:

3 “(D) provide recommendations to the Sec-  
4 retary on policies and procedures to complete  
5 the steps described in this paragraph in a man-  
6 ner that is consistent with section 2802.”; and

7 (H) by adding at the end the following:

8 “(8) SITUATIONAL AWARENESS AND BIO-  
9 SURVEILLANCE AS A NATIONAL SECURITY PRI-  
10 ORITY.—The Secretary, on a periodic basis as appli-  
11 cable and appropriate, shall meet with the Director  
12 of National Intelligence to inform the development  
13 and capabilities of the nationwide public health situ-  
14 ational awareness and biosurveillance network.”;

15 (5) in subsection (d)—

16 (A) in paragraph (1)—

17 (i) by inserting “environmental health  
18 agencies,” after “public health agencies,”;

19 and

20 (ii) by inserting “immunization pro-  
21 grams,” after “poison control centers,”;

22 and

23 (B) in paragraph (2)—

24 (i) in subparagraph (B), by striking  
25 “and” at the end;



1 (ii) in subparagraph (C), by striking  
2 the period and inserting “; and”; and

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

5 “(D) an implementation plan that may in-  
6 clude measurable steps to achieve the purposes  
7 described in paragraph (1).”; and

8 (C) by striking paragraph (5) and insert-  
9 ing the following:

10 “(5) TECHNICAL ASSISTANCE.—The Secretary  
11 may provide technical assistance to States, localities,  
12 tribes, and territories or a consortium of States, lo-  
13 calities, tribes, and territories receiving an award  
14 under this subsection regarding interoperability and  
15 the technical standards set forth by the Secretary.”;

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

18 (7) by inserting after subsection (e) the fol-  
19 lowing:

20 “(f) PERSONNEL AUTHORITIES.—

21 “(1) SPECIALLY QUALIFIED PERSONNEL.—In  
22 addition to any other personnel authorities, to carry  
23 out subsections (b) and (c), the Secretary may—

24 “(A) appoint highly qualified individuals to  
25 scientific or professional positions at the Cen-

1           ters for Disease Control and Prevention, not to  
2           exceed 30 such employees at any time (specific  
3           to positions authorized by this subsection), with  
4           expertise in capabilities relevant to biosurveil-  
5           lance and situational awareness, such as experts  
6           in informatics and data analytics (including ex-  
7           perts in prediction, modeling, or forecasting),  
8           and other related scientific or technical fields;  
9           and

10           “(B) compensate individuals appointed  
11           under subparagraph (A) in the same manner  
12           and subject to the same terms and conditions in  
13           which individuals appointed under 9903 of title  
14           5, United States Code, are compensated, with-  
15           out regard to the provisions of chapter 51 and  
16           subchapter III of chapter 53 of such title relat-  
17           ing to classification and General Schedule pay  
18           rates.

19           “(2) LIMITATIONS.—The Secretary shall exer-  
20           cise the authority under paragraph (1) in a manner  
21           that is consistent with the limitations described in  
22           section 319F–1(e)(2).

23           “(g) TIMELINE.—The Secretary shall accomplish the  
24           purposes under subsections (b) and (c) no later than Sep-  
25           tember 30, 2023, and shall provide a justification to the

1 congressional committees of jurisdiction for any missed or  
2 delayed implementation of measurable steps identified  
3 under subsection (c)(6)(A)(iii).

4 “(h) INDEPENDENT EVALUATION.—Not later than 3  
5 years after the date of enactment of the Pandemic and  
6 All-Hazards Preparedness and Advancing Innovation Act  
7 of 2018, the Comptroller General of the United States  
8 shall conduct an independent evaluation, and submit to  
9 the Secretary and the congressional committees of juris-  
10 diction a report concerning the activities conducted under  
11 subsections (b) and (c), and provide recommendations, as  
12 applicable and appropriate, on necessary improvements to  
13 the biosurveillance and situational awareness network.”.

14 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-  
15 section (i) of section 319D of the Public Health Service  
16 Act (42 U.S.C. 247d–4), as redesignated by subsection  
17 (a)(6), is amended by striking “\$138,300,000 for each of  
18 fiscal years 2014 through 2018” and inserting  
19 “\$161,800,000 for each of fiscal years 2019 through  
20 2023”.

21 (c) BIOLOGICAL THREAT DETECTION REPORT.—The  
22 Secretary of Health and Human Services shall, in coordi-  
23 nation with the Secretary of Defense and the Secretary  
24 of Homeland Security, not later than 180 days after the  
25 date of enactment of this Act, report to the Committee

1 on Energy and Commerce, the Committee on Armed Serv-  
2 ices, and the Committee on Homeland Security of the  
3 House of Representatives and the Committee on Health,  
4 Education, Labor, and Pensions, the Committee on Armed  
5 Services, and the Committee on Homeland Security and  
6 Governmental Affairs of the Senate on the state of Fed-  
7 eral biological threat detection efforts, including the fol-  
8 lowing—

9           (1) an identification of technological, oper-  
10          ational, and programmatic successes and failures of  
11          domestic detection programs supported by Federal  
12          departments and agencies for intentionally-intro-  
13          duced or accidentally-released biological threat  
14          agents and naturally occurring infectious diseases;

15          (2) a description of Federal efforts to facilitate  
16          the exchange of information related to the informa-  
17          tion described in paragraph (1) among Federal de-  
18          partments and agencies that utilize biological threat  
19          detection technology;

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

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

1 (B) recover live biological agents from col-  
2 lection devices;

3 (C) determine the geographical distribution  
4 of biological agents;

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

8 (E) provide advanced molecular diagnostics  
9 to State, local, tribal, and territorial public  
10 health and other laboratories that support bio-  
11 logical threat detection activities;

12 (4) a description of Federal interagency coordi-  
13 nation related to biological threat detection;

14 (5) a description of efforts by Federal depart-  
15 ments and agencies that utilize biological threat de-  
16 tection technology to collaborate with State, local,  
17 tribal, and territorial public health laboratories and  
18 other users of biological threat detection systems, in-  
19 cluding collaboration regarding the development of—

20 (A) biological threat detection require-  
21 ments or standards;

22 (B) a standardized integration strategy;

23 (C) training requirements or guidelines;

24 (D) guidelines for a coordinated public  
25 health response, including preparedness capa-

1           bilities, and, as applicable, for coordination with  
2           public health surveillance systems; and

3                   (E) a coordinated environmental remedi-  
4           ation plan, as applicable; and

5           (6) recommendations related to research, ad-  
6           vanced research, development, and procurement for  
7           Federal departments and agencies to improve and  
8           enhance biological threat detection systems, includ-  
9           ing recommendations on the transfer of biological  
10          threat detection technology among Federal depart-  
11          ments and agencies, as necessary and appropriate.

12 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**  
13                   **HEALTH EMERGENCY RAPID RESPONSE**  
14                   **FUND.**

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

17                   (1) in subsection (b)—

18                           (A) in paragraph (1)—

19                                   (i) in the first sentence, by inserting  
20                                   “or if the Secretary determines there is the  
21                                   significant potential for a public health  
22                                   emergency, to allow the Secretary to rap-  
23                                   idly respond to the immediate needs result-  
24                                   ing from such public health emergency or

1 potential public health emergency” before  
2 the period; and

3 (ii) by inserting “The Secretary shall  
4 plan for the expedited distribution of funds  
5 to appropriate agencies and entities.” after  
6 the first sentence;

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

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

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

13 “(A) facilitate coordination between and  
14 among Federal, State, local, tribal, and terri-  
15 torial entities and public and private health  
16 care entities that the Secretary determines may  
17 be affected by a public health emergency or po-  
18 tential public health emergency referred to in  
19 paragraph (1) (including communication of  
20 such entities with relevant international enti-  
21 ties, as applicable);

22 “(B) make grants, provide for awards,  
23 enter into contracts, and conduct supportive in-  
24 vestigations pertaining to a public health emer-  
25 gency or potential public health emergency, in-

1 including further supporting programs under sec-  
2 tion 319C-1, 319C-2, or 319C-3;

3 “(C) facilitate and accelerate, as applica-  
4 ble, advanced research and development of secu-  
5 rity countermeasures (as defined in section  
6 319F-2), qualified countermeasures (as defined  
7 in section 319F-1), or qualified pandemic or  
8 epidemic products (as defined in section 319F-  
9 3), that are applicable to the public health  
10 emergency or potential public health emergency  
11 under paragraph (1);

12 “(D) strengthen biosurveillance capabilities  
13 and laboratory capacity to identify, collect, and  
14 analyze information regarding such public  
15 health emergency or potential public health  
16 emergency, including the systems under section  
17 319D;

18 “(E) support initial emergency operations  
19 and assets related to preparation and deploy-  
20 ment of intermittent disaster response per-  
21 sonnel under section 2812, and the Medical Re-  
22 serve Corps under section 2813; and

23 “(F) carry out other activities, as the Sec-  
24 retary determines applicable and appropriate.”;  
25 and



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

3 “(4) REVIEW.—Not later than 2 years after the  
4 date of enactment of the Pandemic and All-Hazards  
5 Preparedness and Advancing Innovation Act of  
6 2018, the Secretary, in coordination with the Assist-  
7 ant Secretary for Preparedness and Response, shall  
8 conduct a review of the Fund under this section, and  
9 provide recommendations to the Committee on  
10 Health, Education, Labor, and Pensions and the  
11 Committee on Appropriations of the Senate and the  
12 Committee on Energy and Commerce and the Com-  
13 mittee on Appropriations of the House of Represent-  
14 atives on policies to improve such Fund for the uses  
15 described in paragraph (2).

16 “(5) GAO REPORT.—Not later than 4 years  
17 after the date of enactment of the Pandemic and  
18 All-Hazards Preparedness and Advancing Innovation  
19 Act of 2018, the Comptroller General of the United  
20 States shall—

21 “(A) conduct a review of the Fund under  
22 this section, including its uses and the re-  
23 sources available in the Fund; and

24 “(B) submit to the Committee on Health,  
25 Education, Labor, and Pensions of the Senate

1 and the Committee on Energy and Commerce  
2 of the House of Representatives a report on  
3 such review, including recommendations related  
4 to such review, as applicable.”; and

5 (2) in subsection (c)—

6 (A) by inserting “rapidly respond to public  
7 health emergencies or potential public health  
8 emergencies and” after “used to”; and

9 (B) by striking “section.” and inserting  
10 “Act or funds otherwise provided for emergency  
11 response.”.

12 **SEC. 207. IMPROVING ALL-HAZARDS PREPAREDNESS AND**  
13 **RESPONSE BY PUBLIC HEALTH EMERGENCY**  
14 **VOLUNTEERS.**

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

17 (1) in the section heading, by striking  
18 “**HEALTH PROFESSIONS VOLUNTEERS**” and in-  
19 serting “**VOLUNTEER HEALTH PROFESSIONAL**”;

20 (2) in subsection (a), by adding at the end the  
21 following: “Such health care professionals may in-  
22 clude members of the National Disaster Medical  
23 System, members of the Medical Reserve Corps, and  
24 individual health care professionals.”;

1           (3) in subsection (i) by adding at the end “In  
2           order to inform the development of such mechanisms  
3           by States, the Secretary shall make available infor-  
4           mation and material provided by States that have  
5           developed mechanisms to waive the application of li-  
6           censing requirements to applicable health profes-  
7           sionals seeking to provide medical services during a  
8           public health emergency. Such information shall be  
9           made publicly available in a manner that does not  
10          compromise national security.”; and

11          (4) in subsection (k) by striking “2014 through  
12          2018” and inserting “2019 through 2023”.

13          (b) ALL-HAZARDS PUBLIC HEALTH EMERGENCY  
14          PREPAREDNESS AND RESPONSE PLAN.—Section 319C–  
15          1(b)(2)(A)(iv) of the Public Health Service Act (42 U.S.C.  
16          247d–3a(b)(2)(A)(iv)) is amended to read as follows:

17                 “(iv) a description of the mechanism the  
18                 entity will implement to utilize the Emergency  
19                 Management Assistance Compact, or other mu-  
20                 tual aid agreement, for medical and public  
21                 health mutual aid, and, as appropriate, the ac-  
22                 tivities such entity will implement pursuant to  
23                 section 319I to improve enrollment and coordi-  
24                 nation of volunteer health care professionals

1 seeking to provide medical services during a  
2 public health emergency, which may include—

3 “(I) providing a public method of  
4 communication for purposes of volunteer  
5 coordination (such as a phone number);

6 “(II) providing for optional registra-  
7 tion to participate in volunteer services  
8 during processes related to State medical  
9 licensing, registration, or certification or  
10 renewal of such licensing, registration or  
11 certification; or

12 “(III) other mechanisms as the State  
13 determines appropriate;”.

14 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**  
15 **TEER HEALTH CARE PROFESSIONALS.**

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

19 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**  
20 **ING A PUBLIC HEALTH EMERGENCY.**

21 “(a) LIMITATION ON LIABILITY.—Notwithstanding  
22 any other provision of law, a health care professional who  
23 is a member of the Medical Reserve Corps under section  
24 2813 or who is included in the Emergency System for Ad-

1 vance Registration of Volunteer Health Professionals  
2 under section 319I and who—

3 “(1) is responding—

4 “(A) to a public health emergency deter-  
5 mined under section 319(a), during the initial  
6 period of not more than 90 days (as determined  
7 by the Secretary) of the public health emer-  
8 gency determination (excluding any period cov-  
9 ered by a renewal of such determination); or

10 “(B) to a major disaster or an emergency  
11 as declared by the President under section 401  
12 of the Robert T. Stafford Disaster Relief and  
13 Emergency Assistance Act (42 U.S.C. 5170) or  
14 under section 201 of the National Emergencies  
15 Act (50 U.S.C.1621) during the initial period of  
16 such declaration; and

17 “(2) is alleged to be liable for an act or omis-  
18 sion—

19 “(A) during the initial period of a deter-  
20 mination or declaration described in paragraph  
21 (1) and related to the treatment of individuals  
22 in need of health care services due to such pub-  
23 lic health emergency, major disaster, or emer-  
24 gency;

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

3           “(C) in the health care professional’s ca-  
4           pacity as a member of the Medical Reserve  
5           Corps or a professional included in the Emer-  
6           gency System for Advance Registration of Vol-  
7           unteer Health Professionals under section 319I;  
8           and

9           “(D) in the course of providing services  
10          that are within the scope of the license, reg-  
11          istration, or certification of the professional, as  
12          defined by the State of licensure, registration,  
13          or certification; and

14          “(3) prior to the rendering of such act or omis-  
15          sion, was authorized by the State’s authorization of  
16          deploying such State’s Emergency System for Ad-  
17          vance Registration of Volunteer Health Professionals  
18          described in section 319I or the Medical Reserve  
19          Corps established under section 2813, to provide  
20          health care services,

21 shall be subject only to the State liability laws of the State  
22 in which such act or omission occurred, in the same man-  
23 ner and to the same extent as a similar health care profes-  
24 sional who is a resident of such State would be subject

1 to such State laws, except with respect to the licensure,  
2 registration, and certification of such individual.

3 “(b) VOLUNTEER PROTECTION ACT.—Nothing in  
4 this section shall be construed to affect an individual’s  
5 right to protections under the Volunteer Protection Act  
6 of 1997.

7 “(c) PREEMPTION.—This section shall supercede the  
8 laws of any State that would subject a health care profes-  
9 sional described in subsection (a) to the liability laws of  
10 any State other than the State liability laws to which such  
11 individual is subject pursuant to such subsection.

12 “(d) DEFINITIONS.—In this section:

13 “(1) The term ‘health care professional’ means  
14 an individual licensed, registered, or certified under  
15 Federal or State laws or regulations to provide  
16 health care services.

17 “(2) The term ‘health care services’ means any  
18 services provided by a health care professional, or by  
19 any individual working under the supervision of a  
20 health care professional, that relate to—

21 “(A) the diagnosis, prevention, or treat-  
22 ment of any human disease or impairment; or

23 “(B) the assessment or care of the health  
24 of human beings.

25 “(e) EFFECTIVE DATE.—

1           “(1) IN GENERAL.—This section shall take ef-  
2           fect 90 days after the date of the enactment of the  
3           Pandemic and All-Hazards Preparedness and Ad-  
4           vancing Innovation Act of 2018.

5           “(2) APPLICATION.—This section shall apply to  
6           a claim for harm only if the act or omission that  
7           caused such harm occurred on or after the effective  
8           date described in paragraph (1).”.

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

12               (1) the number of health care providers who  
13               register under the Emergency System for Advance  
14               Registration of Volunteer Health Professionals  
15               under section 319I of the Public Health Service Act  
16               (42 U.S.C. 247d–7b) in advance to provide services  
17               during a public health emergency;

18               (2) the number of health care providers who are  
19               credentialed to provide services during the period of  
20               a public health emergency declaration, including  
21               those who are credentialed through programs estab-  
22               lished in the Emergency System for Advance Reg-  
23               istration of Volunteer Health Professionals under  
24               such section 319I and those credentialed by authori-



1 ties within the State in which the emergency oc-  
2 curred;

3 (3) the average time to verify the credentials of  
4 a health care provider during the period of a public  
5 health emergency declaration, including the average  
6 time pursuant to the Emergency System for Ad-  
7 vance Registration of Volunteer Health Professionals  
8 under such section 319I and for an individual's cre-  
9 dentials to be verified by an authority within the  
10 State; and

11 (4) the Emergency System for Advance Reg-  
12 istration of Volunteer Health Professionals program  
13 in States, including whether physician or medical  
14 groups, associations, or other relevant provider orga-  
15 nizations utilize such program for purposes of volun-  
16 teering during public health emergencies.

17 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**  
18 **PLY.**

19 Not later than 1 year after the date of the enactment  
20 of this Act, the Secretary of Health and Human Services  
21 shall submit to Congress a report containing recommenda-  
22 tions related to maintaining an adequate national blood  
23 supply, including—

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

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

6 (3) implementation of the transfusion trans-  
7 mission monitoring system; and

8 (4) other measures to promote safety and inno-  
9 vation, such as the development, use, or implementa-  
10 tion of new technologies, processes, and procedures  
11 to improve the safety and reliability of the blood  
12 supply.

13 **SEC. 210. REPORT ON THE PUBLIC HEALTH PREPARED-**  
14 **NESS AND RESPONSE CAPABILITIES AND CA-**  
15 **PACITIES OF HOSPITALS, LONG-TERM CARE**  
16 **FACILITIES, AND OTHER HEALTH CARE FA-**  
17 **CILITIES.**

18 (a) STUDY.—

19 (1) IN GENERAL.—Not later than one year  
20 after the date of enactment of this Act, the Sec-  
21 retary of Health and Human Services shall enter  
22 into an agreement with an appropriate entity to con-  
23 duct a study regarding the public health prepared-  
24 ness and response capabilities and medical surge ca-  
25 pacities of hospitals, long-term care facilities, and

1 other health care facilities to prepare for, and re-  
2 spond to, public health emergencies, including nat-  
3 ural disasters.

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

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

12 (A) an evaluation of the current bench-  
13 marks and objective standards, as applicable,  
14 related to programs that support hospitals,  
15 long-term care facilities, and other health care  
16 facilities, and their effect on improving public  
17 health preparedness and response capabilities  
18 and medical surge capacities, including the  
19 Hospital Preparedness Program, the Public  
20 Health Emergency Preparedness cooperative  
21 agreements, and the Regional Health Care  
22 Emergency Preparedness and Response Sys-  
23 tems under section 319C–3 of the Public  
24 Health Service Act (as added by section 203);

1 (B) the identification of gaps in prepared-  
2 ness, including with respect to such benchmarks  
3 and objective standards, such as those identified  
4 during recent public health emergencies, for  
5 hospitals, long-term care facilities, and other  
6 health care facilities to address future potential  
7 public health threats;

8 (C) an evaluation of coordination efforts  
9 between the recipients of Federal funding for  
10 programs described in subparagraph (A) and  
11 entities with expertise in emergency power sys-  
12 tems and other critical infrastructure partners  
13 during a public health emergency, to ensure a  
14 functioning critical infrastructure, to the great-  
15 est extent practicable, during a public health  
16 emergency;

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

24 (E) an evaluation of current public health  
25 preparedness and response capabilities and

1           medical surge capacities related to at-risk indi-  
2           viduals during public health emergencies, in-  
3           cluding an identification of gaps in such pre-  
4           paredness as they relate to such individuals.

5           (b) REPORT.—

6           (1) IN GENERAL.—The agreement under sub-  
7           section (a) shall require the entity to submit to the  
8           Secretary of Health and Human Services and the  
9           congressional committees of jurisdiction, not later  
10          than 3 years after the date of enactment of this Act,  
11          a report on the results of the study conducted pur-  
12          suant to this section.

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

15                (A) describe the findings and conclusions  
16                of the evaluation conducted pursuant to sub-  
17                section (a); and

18                (B) provide recommendations for improv-  
19                ing public health preparedness and response ca-  
20                pability and medical surge capacity for hos-  
21                pitals, long-term care facilities, and other health  
22                care facilities, including—

23                       (i) improving the existing benchmarks  
24                       and objective standards for the Federal  
25                       grant programs described in subsection

1 (a)(3)(A) or developing new benchmarks  
2 and standards for such programs; and  
3 (ii) identifying best practices for im-  
4 proving public health preparedness and re-  
5 sponse programs and medical surge capac-  
6 ity at hospitals, long-term care facilities,  
7 and other health care facilities, including  
8 recommendations for the evaluation under  
9 subparagraphs (C) and (D) of subsection  
10 (a)(3).

11 **TITLE III—REACHING ALL**  
12 **COMMUNITIES**

13 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**  
14 **GENCY RESPONSE WORKFORCE.**

15 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

16 (1) STRENGTHENING THE NATIONAL DISASTER  
17 MEDICAL SYSTEM.—Clause (ii) of section  
18 2812(a)(3)(A) of the Public Health Service Act (42  
19 U.S.C. 300hh–11(a)(3)(A)) is amended to read as  
20 follows:

21 “(ii) be present at locations, and for  
22 limited periods of time, specified by the  
23 Secretary on the basis that the Secretary  
24 has determined that a location is at risk of  
25 a public health emergency during the time

1 specified, or there is a significant potential  
2 for a public health emergency.”.

3 (2) REVIEW OF THE NATIONAL DISASTER MED-  
4 ICAL SYSTEM.—Section 2812(b)(2) of the Public  
5 Health Service Act (42 U.S.C. 300hh–11(b)(2)) is  
6 amended to read as follows:

7 “(2) JOINT REVIEW AND MEDICAL SURGE CA-  
8 PACITY STRATEGIC PLAN.—

9 “(A) REVIEW.—Not later than 180 days  
10 after the date of enactment of the Pandemic  
11 and All-Hazards Preparedness and Advancing  
12 Innovation Act of 2018, the Secretary, in co-  
13 ordination with the Secretary of Homeland Se-  
14 curity, the Secretary of Defense, and the Sec-  
15 retary of Veterans Affairs, shall conduct a joint  
16 review of the National Disaster Medical System.  
17 Such review shall include—

18 “(i) an evaluation of medical surge ca-  
19 pacity, as described in section 2803(a);

20 “(ii) an assessment of the available  
21 workforce of the intermittent disaster re-  
22 sponse personnel described in subsection  
23 (c);

24 “(iii) the capacity of the workforce de-  
25 scribed in clause (ii) to respond to all haz-

1 ards, including capacity to simultaneously  
2 respond to multiple public health emer-  
3 gencies and the capacity to respond to a  
4 nationwide public health emergency;

5 “(iv) the effectiveness of efforts to re-  
6 cruit, retain, and train such workforce; and

7 “(v) gaps that may exist in such  
8 workforce and recommendations for ad-  
9 dressing such gaps.

10 “(B) UPDATES.—As part of the National  
11 Health Security Strategy under section 2802,  
12 the Secretary shall update the findings from the  
13 review under subparagraph (A) and provide rec-  
14 ommendations to modify the policies of the Na-  
15 tional Disaster Medical System as necessary.”.

16 (3) NOTIFICATION OF SHORTAGE.—Section  
17 2812(c) of the Public Health Service Act (42 U.S.C.  
18 300hh–11(c)) is amended by adding at the end the  
19 following:

20 “(3) NOTIFICATION.—Not later than 30 days  
21 after the date on which the Secretary determines the  
22 number of intermittent disaster-response personnel  
23 of the National Disaster Medical System is insuffi-  
24 cient to address a public health emergency or poten-  
25 tial public health emergency, the Secretary shall sub-



1       mit to the congressional committees of jurisdiction a  
2       notification detailing—

3               “(A) the impact such shortage could have  
4               on meeting public health needs and emergency  
5               medical personnel needs during a public health  
6               emergency; and

7               “(B) any identified measures to address  
8               such shortage.

9       “(4) CERTAIN APPOINTMENTS.—

10              “(A) IN GENERAL.—If the Secretary deter-  
11              mines that the number of intermittent disaster  
12              response personnel within the National Disaster  
13              Medical System under this section is insuffi-  
14              cient to address a public health emergency or  
15              potential public health emergency, the Secretary  
16              may appoint candidates directly to personnel  
17              positions for intermittent disaster response  
18              within such system. The Secretary shall provide  
19              updates on the number of vacant or unfilled po-  
20              sitions within such system to the congressional  
21              committees of jurisdiction each quarter for  
22              which this authority is in effect.

23              “(B) SUNSET.—The authority under this  
24              paragraph shall expire on September 30,  
25              2021.”.

1           (4) AUTHORIZATION OF APPROPRIATIONS.—  
2           Section 2812(g) of the Public Health Service Act  
3           (42 U.S.C. 300hh–11(g)) is amended by striking  
4           “\$52,700,000 for each of fiscal years 2014 through  
5           2018” and inserting “\$57,400,000 for each of fiscal  
6           years 2019 through 2023”.

7           (b) VOLUNTEER MEDICAL RESERVE CORPS.—

8           (1) IN GENERAL.—Section 2813(a) of the Pub-  
9           lic Health Service Act (42 U.S.C. 42 U.S.C. 300hh–  
10          15(a)) is amended by striking the second sentence  
11          and inserting “The Secretary may appoint a Direc-  
12          tor to head the Corps and oversee the activities of  
13          the Corps chapters that exist at the State, local,  
14          tribal, and territorial levels.”.

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

19          (c) STRENGTHENING THE EPIDEMIC INTELLIGENCE  
20          SERVICE.—Section 317F of the Public Health Service Act  
21          (42 U.S.C. Sec. 247b–7) is amended—

22                 (1) in subsection (a)—

23                         (A) in paragraph (1)—

24                                 (i) by inserting “or preparedness and  
25                                 response activities, including rapid re-

1           sponse to public health emergencies and  
2           significant public health threats” after  
3           “conduct prevention activities”; and

4                   (ii) by striking “\$35,000” and insert-  
5           ing “\$50,000”; and

6           (B) in paragraph (2)(B), by striking “3  
7           years” and inserting “2 years”; and

8           (2) in subsection (c)—

9                   (A) by striking “For the purpose of car-  
10           rying out this section” and inserting the fol-  
11           lowing:

12                   “(1) IN GENERAL.—For the purpose of car-  
13           rying out this section, except as described in para-  
14           graph (2)”; and

15                   (B) by adding at the end the following:

16                   “(2) EPIDEMIC INTELLIGENCE SERVICE PRO-  
17           GRAM.—For purposes of carrying out this section  
18           with respect to qualified health professionals serving  
19           in the Epidemic Intelligence Service, as authorized  
20           under section 317G, there are authorized to be ap-  
21           propriated \$1,000,000 for each of fiscal years 2019  
22           through 2023.”.

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

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

5           “(5) SERVICE BENEFIT.—Individuals appointed  
6       to serve under this subsection shall be considered eli-  
7       gible for benefits under part L of title I of the Om-  
8       nibus Crime Control and Safe Streets Act of 1968.  
9       The Secretary shall provide notification to eligible  
10      individuals of any effect such designation may have  
11      on other benefits for which such individual are eligi-  
12      ble, including benefits from private entities.”.

13          (2) PUBLIC SAFETY OFFICER BENEFITS.—Sec-  
14      tion 1204(9) of title I of the Omnibus Crime Control  
15      and Safe Streets Act of 1968 (34 U.S.C. 10284(9))  
16      is amended—

17           (A) in subparagraph (C)(ii), by striking  
18           “or” at the end;

19           (B) in subparagraph (D), by striking the  
20           period and inserting “; or”; and

21           (C) by inserting after subparagraph (D)  
22           the following:

23           “(E) an individual appointed to the Na-  
24           tional Disaster Medical System under section  
25           2812 of the Public Health Service Act (42

1 U.S.C. 300hh–11) who is performing official  
2 duties of the Department of Health and Human  
3 Services, if those official duties are—

4 “(i) related to responding to a public  
5 health emergency or potential public health  
6 emergency, or other activities for which the  
7 Secretary of Health and Human Services  
8 has activated such National Disaster Med-  
9 ical System; and

10 “(ii) determined by the Secretary of  
11 Health and Human Services to be haz-  
12 ardous.”.

13 (3) SUNSET.—The amendments made by para-  
14 graphs (1) and (2) shall cease to have force or effect  
15 on October 1, 2021.

16 (e) MISSION READINESS REPORT TO CONGRESS.—

17 (1) REPORT.—Not later than one year after the  
18 date of enactment of this section, the Comptroller  
19 General of the United States (referred to in this  
20 subsection as the “Comptroller General”) shall sub-  
21 mit to the Committee on Health, Education, Labor,  
22 and Pensions of the Senate and the Committee on  
23 Energy and Commerce of the House of Representa-  
24 tives, a report on the medical surge capacity of the  
25 United States in the event of a public health emer-

1 agency, including the capacity and capability of the  
2 current health care workforce to prepare for, and re-  
3 spond to the full range of public health emergencies  
4 or potential public health emergencies, and rec-  
5 ommendations to address any gaps identified in such  
6 workforce.

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

9 (A) the number of health care providers  
10 who have volunteered to provide health care  
11 services during a public health emergency, in-  
12 cluding members of the National Disaster Med-  
13 ical System, the Disaster Medical Assistant  
14 Teams, the Medical Reserve Corps, and other  
15 volunteer health care professionals in the  
16 verification network pursuant to section 319I of  
17 the Public Health Service Act (42 U.S.C.  
18 247d–7b);

19 (B) the capacity of the workforce described  
20 in subparagraph (A) to respond to a public  
21 health emergency or potential public health  
22 emergency, including the capacity to respond to  
23 multiple concurrent public health emergencies  
24 and the capacity to respond to a nationwide  
25 public health emergency;

1 (C) the preparedness and response capa-  
2 bilities and mission readiness of the workforce  
3 described in subparagraph (A) taking into ac-  
4 count areas of health care expertise and consid-  
5 erations for at-risk individuals (as defined in  
6 section 2802(b)(4)(B) of the Public Health  
7 Service Act (42 U.S.C. 300hh–1(b)(4)(B));

8 (D) an assessment of the effectiveness of  
9 efforts to recruit, retain, and train such work-  
10 force; and

11 (E) identification of gaps that may exist in  
12 such workforce and recommendations for ad-  
13 dressing such gaps, the extent to which the As-  
14 sistant Secretary for Preparedness and Re-  
15 sponse plans to address such gaps, and any rec-  
16 ommendations from the Comptroller General to  
17 address such gaps.

18 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**

19 **PREPAREDNESS AND RESPONSE.**

20 (a) **COORDINATION OF PREPAREDNESS.**—Section  
21 2811(b)(5) of the Public Health Service Act (42 U.S.C.  
22 300hh–10(b)(5)) is amended by adding at the end the fol-  
23 lowing: “Such logistical support shall include working with  
24 other relevant Federal, State, local, tribal, and territorial  
25 public health officials and private sector entities to identify

1 the critical infrastructure assets, systems, and networks  
2 needed for the proper functioning of the health care and  
3 public health sectors that need to be maintained through  
4 any emergency or disaster, including entities capable of  
5 assisting with, responding to, and mitigating the effect of  
6 a public health emergency, including a public health emer-  
7 gency determined by the Secretary pursuant to section  
8 319(a), an emergency or major disaster declared by the  
9 President under the Robert T. Stafford Disaster Relief  
10 and Emergency Assistance Act, or the National Emer-  
11 gencies Act, including by establishing methods to exchange  
12 critical information and deliver products consumed or used  
13 to preserve, protect, or sustain life, health, or safety, and  
14 sharing of specialized expertise.”.

15 (b) MANUFACTURING CAPACITY.—Section  
16 2811(d)(2)(C) of the Public Health Service Act (42  
17 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting “,  
18 and ancillary medical supplies to assist with the utilization  
19 of such countermeasures or products,” after “products”.

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

22 (1) RAPID DELIVERY STUDY.—The Assistant  
23 Secretary for Preparedness and Response may con-  
24 duct a study on issues that have the potential to ad-  
25 versely affect the handling and rapid delivery of



1 medical countermeasures to individuals during public  
2 health emergencies occurring in the United States.

3 (2) NOTICE TO CONGRESS.—Not later than 9  
4 months after the date of the enactment of this Act,  
5 the Assistant Secretary for Preparedness and Re-  
6 sponse shall notify the Committee on Energy and  
7 Commerce of the House of Representatives and the  
8 Committee on Health, Education, Labor, and Pen-  
9 sions of the Senate if the Assistant Secretary for  
10 Preparedness and Response does not plan to conduct  
11 the study under paragraph (1) and shall provide  
12 such committees a summary explanation for such de-  
13 cision.

14 (3) REPORT TO CONGRESS.—Not later than 1  
15 year after the Assistant Secretary for Preparedness  
16 and Response conducts the study under paragraph  
17 (1), such Assistant Secretary shall submit a report  
18 to the Committee on Energy and Commerce of the  
19 House of Representatives and the Committee on  
20 Health, Education, Labor, and Pensions of the Sen-  
21 ate containing the findings of such study.

22 **SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.**

23 (a) AT-RISK INDIVIDUALS IN THE NATIONAL  
24 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)

1 of the Public Health Service Act (42 U.S.C. 300hh–  
2 1(b)(4)(B)) is amended—

3 (1) by striking “this section and sections 319C–  
4 1, 319F, and 319L,” and inserting “this Act,”; and

5 (2) by striking “special” and inserting “access  
6 or functional”.

7 (b) COUNTERMEASURE CONSIDERATIONS.—Section  
8 319L(c)(6) of the Public Health Service Act (42 U.S.C.  
9 247d–7e(c)(6)) is amended—

10 (1) by striking “elderly” and inserting “senior  
11 citizens”; and

12 (2) by inserting “with relevant characteristics  
13 that warrant consideration during the process of re-  
14 searching and developing such countermeasures and  
15 products” before the period.

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

18 (1) in paragraph (7), by striking “; and” and  
19 inserting a semicolon;

20 (2) in paragraph (8), by striking the period and  
21 inserting “; and”; and

22 (3) by adding at the end the following:

23 “(9) facilitate coordination to ensure that, in  
24 implementing the situational awareness and bio-  
25 surveillance network under section 319D, the Sec-

1       retary considers incorporating data and information  
2       from Federal, State, local, tribal, and territorial  
3       public health officials and entities relevant to detect-  
4       ing emerging public health threats that may affect  
5       at-risk individuals, such as pregnant and postpartum  
6       women and infants, including adverse health out-  
7       comes of such populations related to such emerging  
8       public health threats.”.

9       **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**  
10                   **RESPONSE CONSIDERATIONS FOR CHIL-**  
11                   **DREN.**

12       Part B of title III of the Public Health Service Act  
13       (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
14       tion 319D the following:

15       **“SEC. 319D-1. CHILDREN’S PREPAREDNESS UNIT.**

16       “(a) ENHANCING EMERGENCY PREPAREDNESS FOR  
17       CHILDREN.—The Secretary, acting through the Director  
18       of the Centers for Disease Control and Prevention (re-  
19       ferred to in this subsection as the ‘Director’), shall main-  
20       tain an internal team of experts, to be known as the Chil-  
21       dren’s Preparedness Unit (referred to in this subsection  
22       as the ‘Unit’), to work collaboratively to provide guidance  
23       on the considerations for, and the specific needs of, chil-  
24       dren before, during, and after public health emergencies.  
25       The Unit shall inform the Director regarding emergency

1 preparedness and response efforts pertaining to children  
2 at the Centers for Disease Control and Prevention.

3 “(b) EXPERTISE.—The team described in subsection  
4 (a) shall include one or more pediatricians, which may be  
5 a developmental-behavioral pediatrician, and may also in-  
6 clude behavioral scientists, child psychologists, epidemiolo-  
7 gists, biostatisticians, health communications staff, and  
8 individuals with other areas of expertise, as the Secretary  
9 determines appropriate.

10 “(c) DUTIES.—The team described in subsection (a)  
11 may—

12 “(1) assist State, local, tribal, and territorial  
13 emergency planning and response activities related  
14 to children, which may include developing, identi-  
15 fying, and sharing best practices;

16 “(2) provide technical assistance, training, and  
17 consultation to Federal, State, local, tribal, and ter-  
18 ritorial public health officials to improve prepared-  
19 ness and response capabilities with respect to the  
20 needs of children, including providing such technical  
21 assistance, training, and consultation to eligible enti-  
22 ties in order to support the achievement of measur-  
23 able evidence-based benchmarks and objective stand-  
24 ards applicable to sections 319C–1 and 319C–2;

1           “(3) improve the utilization of methods to in-  
2           corporate the needs of children in planning for and  
3           responding to a public health emergency, including  
4           public awareness of such methods;

5           “(4) coordinate with, and improve, public-pri-  
6           vate partnerships, such as health care coalitions pur-  
7           suant to sections 319C–2 and 319C–3, to address  
8           gaps and inefficiencies in emergency preparedness  
9           and response efforts for children;

10          “(5) provide expertise and input during the de-  
11          velopment of guidance and clinical recommendations  
12          to address the needs of children when preparing for,  
13          and responding to, public health emergencies, includ-  
14          ing pursuant to section 319C–3; and

15          “(6) carry out other duties related to prepared-  
16          ness and response activities for children, as the Sec-  
17          retary determines appropriate.”.

18 **SEC. 305. NATIONAL ADVISORY COMMITTEES ON DISAS-**  
19 **TERS.**

20          (a) REAUTHORIZING THE NATIONAL ADVISORY COM-  
21          MITTEE ON CHILDREN AND DISASTERS.—Section 2811A  
22          of the Public Health Service Act (42 U.S.C. 300hh–10a)  
23          is amended—

24                  (1) in subsection (b)(2), by inserting “, mental  
25                  and behavioral,” after “medical”;

1 (2) in subsection (d)—

2 (A) in paragraph (1), by striking “15” and  
3 inserting “25”; and

4 (B) by striking paragraph (2) and insert-  
5 ing the following:

6 “(2) REQUIRED NON-FEDERAL MEMBERS.—The  
7 Secretary, in consultation with such other heads of  
8 Federal agencies as may be appropriate, shall ap-  
9 point to the Advisory Committee under paragraph  
10 (1) at least 13 individuals, including—

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

14 “(B) at least 2 representatives from State,  
15 local, tribal, or territorial agencies with exper-  
16 tise in pediatric disaster planning, prepared-  
17 ness, response, or recovery;

18 “(C) at least 4 members representing  
19 health care professionals, which may include  
20 members with expertise in pediatric emergency  
21 medicine; pediatric trauma, critical care, or sur-  
22 gery; the treatment of pediatric patients af-  
23 fected by chemical, biological, radiological, or  
24 nuclear agents, including emerging infectious  
25 diseases; pediatric mental or behavioral health

1 related to children affected by a public health  
2 emergency; or pediatric primary care; and

3 “(D) other members as the Secretary de-  
4 termines appropriate, of whom—

5 “(i) at least one such member shall  
6 represent a children’s hospital;

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

10 “(iii) at least one such member shall  
11 be an individual with expertise in children  
12 and youth with special health care needs;  
13 and

14 “(iv) at least one such member shall  
15 be an individual with expertise in the needs  
16 of parents or family caregivers, including  
17 the parents or caregivers of children with  
18 disabilities.”.

19 “(3) FEDERAL MEMBERS.—The Advisory Com-  
20 mittee under paragraph (1) shall include the fol-  
21 lowing Federal members or their designees (who  
22 may be non-voting members, as determined by the  
23 Secretary):

24 “(A) The Assistant Secretary for Pre-  
25 paredness and Response.

1           “(B) The Director of the Biomedical Ad-  
2           vanced Research and Development Authority.

3           “(C) The Director of the Centers for Dis-  
4           ease Control and Prevention.

5           “(D) The Commissioner of Food and  
6           Drugs.

7           “(E) The Director of the National Insti-  
8           tutes of Health.

9           “(F) The Assistant Secretary of the Ad-  
10          ministration for Children and Families.

11          “(G) The Administrator of the Health Re-  
12          sources and Services Administration.

13          “(H) The Administrator of the Federal  
14          Emergency Management Agency.

15          “(I) The Administrator of the Administra-  
16          tion for Community Living.

17          “(J) The Secretary of Education.

18          “(K) Representatives from such Federal  
19          agencies (such as the Substance Abuse and  
20          Mental Health Services Administration and the  
21          Department of Homeland Security) as the Sec-  
22          retary determines appropriate to fulfill the du-  
23          ties of the Advisory Committee under sub-  
24          sections (b) and (c).”.



1           “(4) TERM OF APPOINTMENT.—Each member  
2 of the Advisory Committee appointed under para-  
3 graph (2) shall serve for a term of 3 years, except  
4 that the Secretary may adjust the terms of the Advi-  
5 sory Committee appointees serving on the date of  
6 enactment of the Pandemic and All-Hazards Pre-  
7 paredness and Advancing Innovation Act of 2018, or  
8 appointees who are initially appointed after such  
9 date of enactment, in order to provide for a stag-  
10 gered term of appointment for all members.

11           “(5) CONSECUTIVE APPOINTMENTS; MAXIMUM  
12 TERMS.—A member appointed under paragraph (2)  
13 may serve not more than 3 terms on the Advisory  
14 Committee, and not more than 2 of such terms may  
15 be served consecutively.”;

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

19           (4) by redesignating subsection (f) as sub-  
20 section (g);

21           (5) by inserting after subsection (e) the fol-  
22 lowing:

23           “(f) COORDINATION.—The Secretary shall coordinate  
24 duties and activities authorized under this section in ac-  
25 cordance with section 2811D.”; and

1 (6) in subsection (g), as so redesignated, by  
2 striking “2018” and inserting “2023”.

3 (b) AUTHORIZING THE NATIONAL ADVISORY COM-  
4 MITTEE ON SENIORS AND DISASTERS.—Subtitle B of title  
5 XXVIII of the Public Health Service Act (42 U.S.C.  
6 300hh et seq.) is amended by inserting after section  
7 2811A the following:

8 **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SEN-**  
9  **IORS AND DISASTERS.**

10 “(a) ESTABLISHMENT.—The Secretary, in consulta-  
11 tion with the Secretary of Homeland Security and the Sec-  
12 retary of Veterans Affairs, shall establish an advisory com-  
13 mittee to be known as the National Advisory Committee  
14 on Seniors and Disasters (referred to in this section as  
15 the ‘Advisory Committee’).

16 “(b) DUTIES.—The Advisory Committee shall—

17 “(1) provide advice and consultation with re-  
18 spect to the activities carried out pursuant to section  
19 2814, as applicable and appropriate;

20 “(2) evaluate and provide input with respect to  
21 the medical and public health needs of seniors re-  
22 lated to preparation for, response to, and recovery  
23 from all-hazards emergencies; and

24 “(3) provide advice and consultation with re-  
25 spect to State emergency preparedness and response

1 activities relating to seniors, including related drills  
2 and exercises pursuant to the preparedness goals  
3 under section 2802(b).

4 “(c) ADDITIONAL DUTIES.—The Advisory Committee  
5 may provide advice and recommendations to the Secretary  
6 with respect to seniors and the medical and public health  
7 grants and cooperative agreements as applicable to pre-  
8 paredness and response activities under this title and title  
9 III.

10 “(d) MEMBERSHIP.—

11 “(1) IN GENERAL.—The Secretary, in consulta-  
12 tion with such other heads of agencies as appro-  
13 priate, shall appoint not more than 17 members to  
14 the Advisory Committee. In appointing such mem-  
15 bers, the Secretary shall ensure that the total mem-  
16 bership of the Advisory Committee is an odd num-  
17 ber.

18 “(2) REQUIRED MEMBERS.—The Advisory  
19 Committee shall include Federal members or their  
20 designees (who may be non-voting members, as de-  
21 termined by the Secretary) and non-Federal mem-  
22 bers, as follows:

23 “(A) The Assistant Secretary for Pre-  
24 paredness and Response.

1           “(B) The Director of the Biomedical Ad-  
2           vanced Research and Development Authority.

3           “(C) The Director of the Centers for Dis-  
4           ease Control and Prevention.

5           “(D) The Commissioner of Food and  
6           Drugs.

7           “(E) The Director of the National Insti-  
8           tutes of Health.

9           “(F) The Administrator of the Centers for  
10          Medicare & Medicaid Services.

11          “(G) The Administrator of the Administra-  
12          tion for Community Living.

13          “(H) The Administrator of the Federal  
14          Emergency Management Agency.

15          “(I) The Under Secretary for Health of  
16          the Department of Veterans Affairs.

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

21          “(K) At least 2 representatives of State,  
22          local, territorial, or tribal agencies with exper-  
23          tise in geriatric disaster planning, preparedness,  
24          response, or recovery.

1           “(L) Representatives of such other Federal  
2 agencies (such as the Department of Energy  
3 and the Department of Homeland Security) as  
4 the Secretary determines necessary to fulfill the  
5 duties of the Advisory Committee.

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

9           “(f) COORDINATION.—The Secretary shall coordinate  
10 duties and activities authorized under this section in ac-  
11 cordance with section 2811D.

12          “(g) SUNSET.—

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

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

19          “(c) NATIONAL ADVISORY COMMITTEE ON INDIVID-  
20 UALS WITH DISABILITIES AND DISASTERS.—Subtitle B  
21 of title XXVIII of the Public Health Service Act (42  
22 U.S.C. 300hh et seq.), as amended by subsection (b), is  
23 further amended by inserting after section 2811B the fol-  
24 lowing:

1 **“SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON INDIVID-**  
2 **UALS WITH DISABILITIES AND DISASTERS.**

3 “(a) **ESTABLISHMENT.**—The Secretary, in consulta-  
4 tion with the Secretary of Homeland Security, shall estab-  
5 lish a national advisory committee to be known as the Na-  
6 tional Advisory Committee on Individuals with Disabilities  
7 and Disasters (referred to in this section as the ‘Advisory  
8 Committee’).

9 “(b) **DUTIES.**—The Advisory Committee shall—

10 “(1) provide advice and consultation with re-  
11 spect to activities carried out pursuant to section  
12 2814, as applicable and appropriate;

13 “(2) evaluate and provide input with respect to  
14 the medical, public health, and accessibility needs of  
15 individuals with disabilities related to preparation  
16 for, response to, and recovery from all-hazards emer-  
17 gencies; and

18 “(3) provide advice and consultation with re-  
19 spect to State emergency preparedness and response  
20 activities, including related drills and exercises pur-  
21 suant to the preparedness goals under section  
22 2802(b).

23 “(c) **MEMBERSHIP.**—

24 “(1) **IN GENERAL.**—The Secretary, in consulta-  
25 tion with such other heads of agencies and depart-  
26 ments as appropriate, shall appoint not more than

1 17 members to the Advisory Committee. In appoint-  
2 ing such members, the Secretary shall ensure that  
3 the total membership of the Advisory Committee is  
4 an odd number.

5 “(2) REQUIRED MEMBERS.—The Advisory  
6 Committee shall include Federal members or their  
7 designees (who may be non-voting members, as de-  
8 termined by the Secretary) and non-Federal mem-  
9 bers, as follows:

10 “(A) The Assistant Secretary for Pre-  
11 paredness and Response.

12 “(B) The Administrator of the Administra-  
13 tion for Community Living.

14 “(C) The Director of the Biomedical Ad-  
15 vanced Research and Development Authority.

16 “(D) The Director of the Centers for Dis-  
17 ease Control and Prevention.

18 “(E) The Commissioner of Food and  
19 Drugs.

20 “(F) The Director of the National Insti-  
21 tutes of Health.

22 “(G) The Administrator of the Federal  
23 Emergency Management Agency.

24 “(H) The Chair of the National Council on  
25 Disability.

1           “(I) The Chair of the United States Access  
2 Board.

3           “(J) The Under Secretary for Health of  
4 the Department of Veterans Affairs.

5           “(K) At least 2 non-Federal health care  
6 professionals with expertise in disability accessi-  
7 bility before, during, and after disasters, med-  
8 ical and mass care disaster planning, prepared-  
9 ness, response, or recovery.

10           “(L) At least 2 representatives from State,  
11 local, territorial, or tribal agencies with exper-  
12 tise in disaster planning, preparedness, re-  
13 sponse, or recovery for individuals with disabil-  
14 ities.

15           “(M) At least 2 individuals with a dis-  
16 ability with expertise in disaster planning, pre-  
17 paredness, response, or recovery for individuals  
18 with disabilities.

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

22           “(e) DISABILITY DEFINED.—For purposes of this  
23 section, the term ‘disability’ has the meaning given such  
24 term in section 3 of the Americans with Disabilities Act  
25 of 1990.



1           “(f) COORDINATION.—The Secretary shall coordinate  
2 duties and activities authorized under this section in ac-  
3 cordance with section 2811D.

4           “(g) SUNSET.—

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

7                 “(2) RECOMMENDATION.—Not later than Octo-  
8 ber 1, 2022, the Secretary shall submit to Congress  
9 a recommendation on whether the Advisory Com-  
10 mittee should be extended.”.

11           (d) ADVISORY COMMITTEE COORDINATION.—Sub-  
12 title B of title XXVIII of the Public Health Service Act  
13 (42 U.S.C. 300hh et seq.), as amended by subsection (c),  
14 is further amended by inserting after section 2811C the  
15 following:

16           **“SEC. 2811D. ADVISORY COMMITTEE COORDINATION.**

17                 “(a) IN GENERAL.—The Secretary shall coordinate  
18 duties and activities authorized under sections 2811A,  
19 2811B, and 2811C, and make efforts to reduce unneces-  
20 sary or duplicative reporting, or unnecessary duplicative  
21 meetings and recommendations under such sections, as  
22 practicable. Members of the advisory committees author-  
23 ized under such sections, or their designees, shall annually  
24 meet to coordinate any recommendations, as appropriate,  
25 that may be similar, duplicative, or overlapping with re-

1 spect to addressing the needs of children, seniors, and in-  
2 dividuals with disabilities during public health emer-  
3 gencies. If such coordination occurs through an in-person  
4 meeting, it shall not be considered the required in-person  
5 meetings under any of sections 2811A(e), 2811B(e), or  
6 2811C(d).

7 “(b) COORDINATION AND ALIGNMENT.—The Sec-  
8 retary, acting through the employee designated pursuant  
9 to section 2814, shall align preparedness and response  
10 programs or activities to address similar, dual, or overlap-  
11 ping needs of children, seniors, and individuals with dis-  
12 abilities, and any challenges in preparing for and respond-  
13 ing to such needs.

14 “(c) NOTIFICATION.—The Secretary shall annually  
15 notify the congressional committees of jurisdiction regard-  
16 ing the steps taken to coordinate, as appropriate, the rec-  
17 ommendations under this section, and provide a summary  
18 description of such coordination.”.

19 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**  
20 **AND DRILLS.**

21 Not later than 2 years after the date of enactment  
22 of this Act, the Secretary of Health and Human Services  
23 shall issue final guidance regarding the ability of per-  
24 sonnel funded by programs authorized under this Act (in-  
25 cluding the amendments made by this Act) to participate

1 in drills and operational exercises related to all-hazards  
2 medical and public health preparedness and response.  
3 Such drills and operational exercises may include activities  
4 that incorporate medical surge capacity planning, medical  
5 countermeasure distribution and administration, and pre-  
6 paring for and responding to identified threats for that  
7 region. Such personnel may include State, local, tribal,  
8 and territorial public health department or agency per-  
9 sonnel funded under this Act (including the amendments  
10 made by this Act). The Secretary shall consult with the  
11 Department of Homeland Security, the Department of  
12 Defense, the Department of Veterans Affairs, and other  
13 applicable Federal departments and agencies as necessary  
14 and appropriate in the development of such guidance. The  
15 Secretary shall make the guidance available on the inter-  
16 net website of the Department of Health and Human  
17 Services.

18 **TITLE IV—PRIORITIZING A**  
19 **THREAT-BASED APPROACH**

20 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**  
21 **RESPONSE.**

22 Section 2811 of the Public Health Service Act (42  
23 U.S.C. 300hh–10) is amended—  
24 (1) in subsection (b)—

1 (A) in the matter preceding paragraph (1)  
2 by inserting “utilize experience related to public  
3 health emergency preparedness and response,  
4 biodefense, medical countermeasures, and other  
5 relevant topics to” after “shall”; and

6 (B) in paragraph (4) by adding at the end  
7 the following:

8 “(I) THREAT AWARENESS.—Coordinate  
9 with the Director of the Centers for Disease  
10 Control and Prevention, the Director of Na-  
11 tional Intelligence, the Secretary of Homeland  
12 Security, the Assistant to the President for Na-  
13 tional Security Affairs, the Secretary of De-  
14 fense, and other relevant Federal officials, such  
15 as the Secretary of Agriculture, to maintain a  
16 current assessment of national security threats  
17 and inform preparedness and response capabili-  
18 ties based on the range of the threats that have  
19 the potential to result in a public health emer-  
20 gency.”; and

21 (2) by adding at the end the following:

22 “(f) PROTECTION OF NATIONAL SECURITY FROM  
23 THREATS.—

24 “(1) IN GENERAL.—In carrying out the duties  
25 under subsection (b)(3), the Assistant Secretary for

1 Preparedness and Response shall implement stra-  
2 tegic initiatives or activities to address threats, in-  
3 cluding pandemic influenza, that pose a significant  
4 level of risk to public health and national security  
5 based on the characteristics of such threat, which  
6 may also include a chemical, biological, radiological,  
7 or nuclear agent, including threats with a significant  
8 potential to become a pandemic. Such initiatives  
9 shall include activities to accelerate and support the  
10 advanced research, development, manufacturing ca-  
11 pacity, procurement, and stockpiling of counter-  
12 measures, including initiatives under section  
13 319L(c)(4)(F). Such activities shall ensure activities  
14 related to readiness to respond to pandemic influ-  
15 enza threats by supporting the development and  
16 manufacturing of influenza virus seeds, clinical trial  
17 lots, and stockpiles of novel influenza strains.

18 “(2) AUTHORIZATION OF APPROPRIATIONS.—

19 “(A) IN GENERAL.—For purposes of car-  
20 rying out this subsection, there is authorized to  
21 be appropriated \$250,000,000 for each of fiscal  
22 years 2019 through 2023.

23 “(B) SUPPLEMENT, NOT SUPPLANT.—

24 Funds appropriated under this subsection shall  
25 be used to supplement and not supplant funds

1 provided under section 319L(f) and section  
2 319F–2(g).

3 “(C) DOCUMENTATION REQUIRED.—The  
4 Assistant Secretary for Preparedness and Re-  
5 sponse shall, as required under subsection  
6 (b)(7), document amounts expended for pur-  
7 poses of carrying out this subsection, including  
8 amounts appropriated to the Public Health and  
9 Social Services Emergency Fund under title II  
10 of Division H of the Consolidated Appropria-  
11 tions Act, 2018 (Public Law 115–141), as ap-  
12 plicable to section 319L(c)(4)(F).”.

13 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
14 **TERMEASURES ENTERPRISE.**

15 (a) IN GENERAL.—Title XXVIII is amended by in-  
16 serting after section 2811 of the Public Health Service  
17 Act (42 U.S.C. 300hh–10) the following:

18 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**  
19 **COUNTERMEASURES ENTERPRISE.**

20 “(a) IN GENERAL.—The Secretary shall establish the  
21 Public Health Emergency Medical Countermeasures En-  
22 terprise (referred to in this section as the ‘PHEMCE’).  
23 The Assistant Secretary for Preparedness and Response  
24 shall serve as chair of the PHEMCE.

1           “(b) MEMBERS.—The PHEMCE shall include each  
2 of the following members, or the designee of such mem-  
3 bers:

4           “(1) The Assistant Secretary for Preparedness  
5 and Response.

6           “(2) The Director of the Centers for Disease  
7 Control and Prevention.

8           “(3) The Director of the National Institutes of  
9 Health.

10           “(4) The Commissioner of Food and Drugs.

11           “(5) The Secretary of Defense.

12           “(6) The Secretary of Homeland Security.

13           “(7) The Secretary of Agriculture.

14           “(8) The Secretary of Veterans Affairs.

15           “(9) The Director of National Intelligence.

16           “(10) Representatives of any other Federal  
17 agency, which may include the Director of the Bio-  
18 medical Advanced Research and Development Au-  
19 thority, the Director of the Strategic National Stock-  
20 pile, the Director of the National Institute of Allergy  
21 and Infectious Diseases, and the Director of the Of-  
22 fice of Public Health Preparedness and Response, as  
23 the Secretary determines appropriate.

24           “(c) FUNCTIONS.—

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

3           “(A) Utilize a process to make rec-  
4 ommendations to the Secretary regarding re-  
5 search, advanced research, development, pro-  
6 curement, stockpiling, deployment, distribution,  
7 and utilization with respect to countermeasures,  
8 as defined in section 319F–2(c), including  
9 prioritization based on the health security needs  
10 of the United States. Such recommendations  
11 shall be informed by, when available and prac-  
12 ticable, the National Health Security Strategy  
13 pursuant to section 2802, the Strategic Na-  
14 tional Stockpile needs pursuant to section  
15 319F–2, and assessments of current national  
16 security threats, including chemical, biological,  
17 radiological and nuclear threats, including  
18 emerging infectious diseases. In the event that  
19 members of the PHEMCE do not agree upon a  
20 recommendation, the Secretary shall provide a  
21 determination regarding such recommendation.

22           “(B) Identify national health security  
23 needs, including gaps in public health prepared-  
24 ness and response related to countermeasures  
25 and challenges to addressing such needs (in-



1 including any regulatory challenges), and support  
2 alignment of countermeasure procurement with  
3 recommendations to address such needs under  
4 subparagraph (A).

5 “(C) Assist the Secretary in developing  
6 strategies related to logistics, deployment, dis-  
7 tribution, dispensing, and use of counter-  
8 measures that may be applicable to the activi-  
9 ties of the strategic national stockpile under  
10 section 319F–2(a).

11 “(D) Provide consultation for the develop-  
12 ment of the strategy and implementation plan  
13 under section 2811(d).

14 “(2) INPUT.—In carrying out subparagraphs  
15 (B) and (C) of paragraph (1), the PHEMCE shall  
16 solicit and consider input from State, local, tribal,  
17 and territorial public health departments or officials,  
18 as appropriate.”.

19 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-  
20 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-  
21 TATION PLAN.—Section 2811(d) of the Public Health  
22 Service Act (42 U.S.C. 300hh–10(d)) is amended—

23 (1) in paragraph (1)—

24 (A) by striking “Not later than 180 days  
25 after the date of enactment of this subsection,

1 and every year thereafter” and inserting “Not  
2 later than March 15, 2020, and biennially  
3 thereafter”; and

4 (B) by striking “Director of Biomedical”  
5 and all that follows through “Food and Drugs”  
6 and inserting “Public Health Emergency Med-  
7 ical Countermeasures Enterprise established  
8 under section 2811–1”; and

9 (2) in paragraph (2)(J)(v), by striking “one-  
10 year period” and inserting “2-year period”.

11 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

12 (a) IN GENERAL.—Section 319F–2(a) of the Public  
13 Health Service Act (42 U.S.C. 247d–6b(a)) is amended—

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

16 (2) in paragraph (1)—

17 (A) by inserting “the Assistant Secretary  
18 for Preparedness and Response and” after “col-  
19 laboration with”;

20 (B) by inserting “and optimize” after  
21 “provide for”;

22 (C) by inserting “and, as informed by ex-  
23 isting recommendations of, or consultations  
24 with, the Public Health Emergency Medical  
25 Countermeasure Enterprise established under

1 section 2811–1, make necessary additions or  
2 modifications to the contents of such stockpile  
3 or stockpiles based on the review conducted  
4 under paragraph (2)” before the period of the  
5 first sentence; and

6 (D) by striking the second sentence;

7 (3) by inserting after paragraph (1) the fol-  
8 lowing:

9 “(2) THREAT-BASED REVIEW.—

10 “(A) IN GENERAL.—The Secretary shall  
11 conduct an annual threat-based review (taking  
12 into account at-risk individuals) of the contents  
13 of the stockpile under paragraph (1), including  
14 non-pharmaceutical supplies, and, in consulta-  
15 tion with the Public Health Emergency Medical  
16 Countermeasures Enterprise established under  
17 section 2811–1, review contents within the  
18 stockpile and assess whether such contents are  
19 consistent with the recommendations made pur-  
20 suant to section 2811–1(c)(1)(A). Such review  
21 shall be submitted annually, beginning on  
22 March 15, 2019, to the Committee on Health,  
23 Education, Labor, and Pensions and the Com-  
24 mittee on Appropriations of the Senate and the  
25 Committee on Energy and Commerce and the

1 Committee on Appropriations of the House of  
2 Representatives, in a manner that does not  
3 compromise national security.

4 “(B) ADDITIONS, MODIFICATIONS, AND  
5 REPLENISHMENTS.—Each annual threat-based  
6 review under subparagraph (A) shall, for each  
7 new or modified countermeasure procurement  
8 or replenishment, provide—

9 “(i) information regarding—

10 “(I) the quantities of the addi-  
11 tional or modified countermeasure  
12 procured for, or contracted to be pro-  
13 cured for, the stockpile;

14 “(II) planning considerations for  
15 appropriate manufacturing capacity  
16 and capability to meet the goals of  
17 such additions or modifications (with-  
18 out disclosing proprietary informa-  
19 tion), including consideration of the  
20 effect such additions or modifications  
21 may have on the availability of such  
22 products and ancillary medical sup-  
23 plies in the health care system;

1 “(III) the presence or lack of a  
2 commercial market for the counter-  
3 measure at the time of procurement;

4 “(IV) the emergency health secu-  
5 rity threat or threats such counter-  
6 measure procurement is intended to  
7 address, including whether such pro-  
8 curement is consistent with meeting  
9 emergency health security needs asso-  
10 ciated with such threat or threats;

11 “(V) an assessment of whether  
12 the emergency health security threat  
13 or threats described in subclause (IV)  
14 could be addressed in a manner that  
15 better utilizes the resources of the  
16 stockpile and permits the greatest  
17 possible increase in the level of emer-  
18 gency preparedness to address such  
19 threats;

20 “(VI) whether such counter-  
21 measure is replenishing an expiring or  
22 expired countermeasure, is a different  
23 countermeasure with the same indica-  
24 tion that is replacing an expiring or

1 expired countermeasure, or is a new  
2 addition to the stockpile;

3 “(VII) a description of how such  
4 additions or modifications align with  
5 projected investments under previous  
6 countermeasures budget plans under  
7 section 2811(b)(7), including expected  
8 life-cycle costs, expenditures related to  
9 countermeasure procurement to ad-  
10 dress the threat or threats described  
11 in subclause (IV), replenishment dates  
12 (including the ability to extend the  
13 maximum shelf life of a counter-  
14 measure), and the manufacturing ca-  
15 pacity required to replenish such  
16 countermeasure; and

17 “(VIII) appropriate protocols and  
18 processes for the deployment, distribu-  
19 tion, or dispensing of the counter-  
20 measure at the State and local level,  
21 including plans for relevant capabili-  
22 ties of State and local entities to dis-  
23 pense, distribute, and administer the  
24 countermeasure; and

1           “(ii) an assurance, which need not be  
2           provided in advance of procurement, that  
3           for each countermeasure procured or re-  
4           plenished under this subsection, the Sec-  
5           retary completed a review addressing each  
6           item listed under this subsection in ad-  
7           vance of such procurement or replenish-  
8           ment.”;

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

10           (A) in subparagraph (A), by inserting  
11           “and the Public Health Emergency Medical  
12           Countermeasures Enterprise established under  
13           section 2811–1” before the semicolon;

14           (B) in subparagraph (C), by inserting “,  
15           and the availability, deployment, dispensing,  
16           and administration of countermeasures” before  
17           the semicolon;

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

20           “(E) devise plans for effective and timely  
21           supply-chain management of the stockpile, in  
22           consultation with the Director of the Centers  
23           for Disease Control and Prevention, the Assist-  
24           ant Secretary for Preparedness and Response,  
25           the Secretary of Transportation, the Secretary

1 of Homeland Security, the Secretary of Vet-  
2 erans Affairs, and the heads of other appro-  
3 priate Federal agencies; State, local, tribal, and  
4 territorial agencies; and the public and private  
5 health care infrastructure, as applicable, taking  
6 into account the manufacturing capacity and  
7 other available sources of products and appro-  
8 priate alternatives to supplies in the stockpile;”;

9 (D) in subparagraph (G), by striking “;  
10 and” and inserting a semicolon;

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

13 (F) by adding at the end the following:

14 “(I) ensure that each countermeasure or  
15 product under consideration for procurement  
16 pursuant to this subsection receives the same  
17 consideration regardless of whether such coun-  
18 termeasure or product receives or had received  
19 funding under section 319L, including with re-  
20 spect to whether the countermeasure or product  
21 is most appropriate to meet the emergency  
22 health security needs of the United States; and

23 “(J) provide assistance, including technical  
24 assistance, to maintain and improve State and  
25 local public health preparedness capabilities to



1 distribute and dispense medical counter-  
2 measures and products from the stockpile, as  
3 appropriate.”; and

4 (5) by adding at the end the following:

5 “(5) GAO REPORT.—

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

15 “(i) an assessment of the comprehen-  
16 siveness and completeness of each annual  
17 threat-based review under paragraph (2),  
18 including whether all newly procured or re-  
19 plenished countermeasures within the  
20 stockpile were described in each annual re-  
21 view, and whether, consistent with para-  
22 graph (2)(B), the Secretary conducted the  
23 necessary internal review in advance of  
24 such procurement or replenishment;

1           “(ii) an assessment of whether the  
2           Secretary established health security and  
3           science-based justifications, and a descrip-  
4           tion of such justifications for procurement  
5           decisions related to health security needs  
6           with respect to the identified threat, for  
7           additions or modifications to the stockpile  
8           based on the information provided in such  
9           reviews under paragraph (2)(B), including  
10          whether such review was conducted prior  
11          to procurement, modification, or replenish-  
12          ment;

13           “(iii) an assessment of the plans de-  
14          veloped by the Secretary for the deploy-  
15          ment, distribution, and dispensing of coun-  
16          termeasures procured, modified, or replen-  
17          ished under paragraph (1), including  
18          whether such plans were developed prior to  
19          procurement, modification, or replenish-  
20          ment;

21           “(iv) an accounting of counter-  
22          measures procured, modified, or replen-  
23          ished under paragraph (1) that received  
24          advanced research and development fund-

1 ing from the Biomedical Advanced Re-  
2 search and Development Authority;

3 “(v) an analysis of how such procure-  
4 ment decisions made progress toward  
5 meeting emergency health security needs  
6 related to the identified threats for coun-  
7 termeasures added, modified, or replen-  
8 ished under paragraph (1);

9 “(vi) a description of the resources ex-  
10 pended related to the procurement of coun-  
11 termeasures (including additions, modifica-  
12 tions, and replenishments) in the stockpile,  
13 and how such expenditures relate to the  
14 ability of the stockpile to meet emergency  
15 health security needs;

16 “(vii) an assessment of the extent to  
17 which additions, modifications, and replen-  
18 ishments reviewed under paragraph (2)  
19 align with previous relevant reports or re-  
20 views by the Secretary or the Comptroller  
21 General;

22 “(viii) with respect to any change in  
23 the Federal organizational management of  
24 the stockpile, an assessment and compari-  
25 son of the processes affected by such

1 change, including planning for potential  
2 countermeasure deployment, distribution,  
3 or dispensing capabilities and processes re-  
4 lated to procurement decisions, use of  
5 stockpiled countermeasures, and use of re-  
6 sources for such activities; and

7 “(ix) an assessment of whether the  
8 processes and procedures described by the  
9 Secretary pursuant to section 403(b) of  
10 the Pandemic and All-Hazards Prepared-  
11 ness and Advancing Innovation Act of  
12 2018 are sufficient to ensure counter-  
13 measures and products under consideration  
14 for procurement pursuant to subsection (a)  
15 receive the same consideration regardless  
16 of whether such countermeasures and  
17 products receive or had received funding  
18 under section 319L, including with respect  
19 to whether such countermeasures and  
20 products are most appropriate to meet the  
21 emergency health security needs of the  
22 United States.

23 “(B) SUBMISSION.—Not later than 6  
24 months after completing a classified version of  
25 the review under subparagraph (A), the Comp-

1 troller General shall submit an unclassified  
2 version of the review to the congressional com-  
3 mittees of jurisdiction.”.

4 (b) ADDITIONAL REPORTING.—In the first threat-  
5 based review submitted after the date of enactment of this  
6 Act pursuant to paragraph (2) of section 319F–2(a) of  
7 the Public Health Service Act (42 U.S.C. 247d–6b(a)), as  
8 amended by subsection (a), the Secretary shall include a  
9 description of the processes and procedures through which  
10 the Director of Strategic National Stockpile and the Di-  
11 rector of the Biomedical Advanced Research and Develop-  
12 ment Authority coordinate with respect to counter-  
13 measures and products procured under such section  
14 319F–2(a), including such processes and procedures in  
15 place to ensure countermeasures and products under con-  
16 sideration for procurement pursuant to such section  
17 319F–2(a) receive the same consideration regardless of  
18 whether such countermeasures and products receive or  
19 had received funding under section 319L of the Public  
20 Health Service Act (42 U.S.C. 247d–7e), or whether such  
21 countermeasures and products are the most appropriate  
22 to meet the emergency health security needs of the United  
23 States.

24 (c) AUTHORIZATION OF APPROPRIATIONS, STRA-  
25 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) of

1 the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))  
2 is amended by striking “\$533,800,000 for each of fiscal  
3 years 2014 through 2018” and inserting “\$610,000,000  
4 for each of fiscal years 2019 through 2023, to remain  
5 available until expended”.

6 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**  
7 **MICROBIAL RESISTANCE, AND OTHER SIG-**  
8 **NIFICANT THREATS.**

9 (a) STRATEGIC INITIATIVES.—Section 319L(c)(4)  
10 (247d–7e(c)(4)) is amended by adding at the end the fol-  
11 lowing:

12 “(F) STRATEGIC INITIATIVES.—The Sec-  
13 retary, acting through the Director of BARDA,  
14 may implement strategic initiatives, including  
15 by building on existing programs and by award-  
16 ing contracts, grants, and cooperative agree-  
17 ments, or entering into other transactions, to  
18 support innovative candidate products in pre-  
19 clinical and clinical development that address  
20 priority, naturally occurring and man-made  
21 threats that, as determined by the Secretary,  
22 pose a significant level of risk to national secu-  
23 rity based on the characteristics of a chemical,  
24 biological, radiological or nuclear threat, or ex-  
25 isting capabilities to respond to such a threat

1 (including medical response and treatment ca-  
2 pabilities and manufacturing infrastructure).  
3 Such initiatives shall accelerate and support the  
4 advanced research, development, and procure-  
5 ment of, countermeasures and products, as ap-  
6 plicable, to address areas including—

7 “(i) chemical, biological, radiological,  
8 or nuclear threats, including emerging in-  
9 fectious diseases, for which insufficient ap-  
10 proved, licensed, or authorized counter-  
11 measures exist, or for which such threat,  
12 or the result of an exposure to such threat,  
13 may become resistant to countermeasures  
14 or existing countermeasures may be ren-  
15 dered ineffective;

16 “(ii) threats that consistently exist or  
17 continually circulate and have significant  
18 potential to become a pandemic, such as  
19 pandemic influenza, which may include the  
20 advanced research and development, manu-  
21 facturing, and appropriate stockpiling of  
22 qualified pandemic or epidemic products,  
23 and products, technologies, or processes to  
24 support the advanced research and devel-  
25 opment of such countermeasures (including

1 multiuse platform technologies for  
2 diagnostics, vaccines, and therapeutics;  
3 virus seeds; clinical trial lots; novel virus  
4 strains; and antigen and adjuvant mate-  
5 rial); and

6 “(iii) threats that may result pri-  
7 marily or secondarily from a chemical, bio-  
8 logical, radiological, or nuclear agent, or  
9 emerging infectious diseases, and which  
10 may present increased treatment complica-  
11 tions such as the occurrence of resistance  
12 to available countermeasures or potential  
13 countermeasures, including antimicrobial  
14 resistant pathogens.”.

15 (b) EMERGING INFECTIOUS DISEASE PROGRAM.—  
16 Section 319L of the Public Health Service Act (42 U.S.C.  
17 247d–7e) is amended—

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

20 (2) by inserting after subsection (c) the fol-  
21 lowing new subsections:

22 “(d) EMERGING INFECTIOUS DISEASE PROGRAM.—

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



1           “(A) advanced research and development  
2           activities for qualified pandemic or epidemic  
3           products; and

4           “(B) manufacturing infrastructure activi-  
5           ties with respect to an emerging infectious dis-  
6           ease.

7           “(2) FUNDING.—

8           “(A) IN GENERAL.—To carry out para-  
9           graph (1), there is authorized to be appro-  
10          priated \$250,000,000 for each of fiscal years  
11          2019 through 2023, to remain available until  
12          expended.

13          “(B) SUPPLEMENT NOT SUPPLANT.—Any  
14          funds provided to the Secretary under this  
15          paragraph shall be used to supplement and not  
16          supplant any other Federal funds provided to  
17          carry out paragraph (1).”.

18   **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**  
19                   **PROGRAM.**

20          Section 351A(k) of the Public Health Service Act (42  
21   U.S.C. 262a(k)) is amended—

22           (1) by striking “The Secretary” and inserting  
23   the following:

24           “(1) IN GENERAL.—The Secretary”; and

25           (2) by adding at the end the following:

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

5           “(A) IN GENERAL.—Not later than 1 year  
6           after the date of the enactment of the Pan-  
7           demic and All-Hazards Preparedness and Ad-  
8           vancing Innovation Act of 2018, the Secretary  
9           shall report to the congressional committees of  
10          jurisdiction on the implementation of rec-  
11          ommendations of the Federal Experts Security  
12          Advisory Panel concerning the select agent pro-  
13          gram.

14          “(B) CONTINUED UPDATES.—The Sec-  
15          retary shall report to the congressional commit-  
16          tees of jurisdiction annually following the sub-  
17          mission of the report under subparagraph (A)  
18          until the recommendations described in such  
19          subparagraph are fully implemented, or a jus-  
20          tification is provided for the delay in, or lack of,  
21          implementation.”.

1 **TITLE V—INCREASING COMMU-**  
2 **NICATION IN MEDICAL COUN-**  
3 **TERMEASURE ADVANCED RE-**  
4 **SEARCH AND DEVELOPMENT**

5 **SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.**

6 Section 2811(b)(7) of the Public Health Service Act  
7 (42 U.S.C. 300hh–10(b)(7)) is amended—

8 (1) in the matter preceding subparagraph (A),  
9 by striking “March 1” and inserting “March 15”;

10 (2) in subparagraph (A)—

11 (A) in clause (ii), by striking “; and” and  
12 inserting “;”; and

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

15 “(iii) procurement, stockpiling, main-  
16 tenance, and potential replenishment (in-  
17 cluding manufacturing capabilities) of all  
18 products in the Strategic National Stock-  
19 pile;

20 “(iv) the availability of technologies  
21 that may assist in the advanced research  
22 and development of countermeasures and  
23 opportunities to use such technologies to  
24 accelerate and navigate challenges unique

1 to countermeasure research and develop-  
2 ment; and

3 “(v) potential deployment, distribu-  
4 tion, and utilization of medical counter-  
5 measures; development of clinical guidance  
6 and emergency use instructions for the use  
7 of medical countermeasures; and, as appli-  
8 cable, potential post-deployment activities  
9 related to medical countermeasures;”;

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

12 (4) by inserting after subparagraph (C), the fol-  
13 lowing:

14 “(D) identify the full range of anticipated  
15 medical countermeasure needs related to re-  
16 search and development, procurement, and  
17 stockpiling, including the potential need for in-  
18 dications, dosing, and administration tech-  
19 nologies, and other countermeasure needs as  
20 applicable and appropriate;”.

21 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**  
22 **MEASURE NOTIFICATIONS.**

23 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL  
24 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of  
25 the Public Health Service Act (42 U.S.C. 247d–

1 6b(c)(2)(C)) is amended by striking “The Secretary and  
2 the Homeland Security Secretary shall promptly notify the  
3 appropriate committees of Congress” and inserting “The  
4 Secretary and the Secretary of Homeland Security shall  
5 send to Congress, on an annual basis, all current material  
6 threat determinations and shall promptly notify the Com-  
7 mittee on Health, Education, Labor, and Pensions and the  
8 Committee on Homeland Security and Governmental Af-  
9 fairs of the Senate and the Committee on Energy and  
10 Commerce and the Committee on Homeland Security of  
11 the House of Representatives”.

12 (b) CONTRACTING COMMUNICATION.—Section 319F-  
13 2(c)(7)(B)(ii)(III) of the Public Health Service Act (42  
14 U.S.C. 247d-6b(c)(7)(B)(ii)(III)) is amended by adding  
15 at the end the following: “The Secretary shall notify the  
16 vendor within 90 days of a determination by the Secretary  
17 to renew, extend, or terminate such contract.”.

18 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**  
19 **PLANS.**

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

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

24 (2) by inserting after paragraph (2) the fol-  
25 lowing:

1           “(3) PUBLICATION.—The Secretary shall make  
2           available on the internet website of the Food and  
3           Drug Administration information regarding regu-  
4           latory management plans, including—

5                   “(A) the process by which an applicant  
6                   may submit a request for a regulatory manage-  
7                   ment plan;

8                   “(B) the timeframe by which the Secretary  
9                   is required to respond to such request;

10                   “(C) the information required for the sub-  
11                   mission of such request;

12                   “(D) a description of the types of develop-  
13                   ment milestones and performance targets that  
14                   could be discussed and included in such plans;  
15                   and

16                   “(E) contact information for beginning the  
17                   regulatory management plan process.”;

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

20                   (A) by striking “paragraph (4)(A)” and in-  
21                   serting “paragraph (5)(A)”; and

22                   (B) by striking “paragraph (4)(B)” and  
23                   inserting “paragraph (5)(B)”; and

1 (4) in paragraph (7)(A), as so redesignated, by  
2 striking “paragraph (3)(A)” and inserting “para-  
3 graph (4)(A)”.

4 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**  
5 **VELOPMENT AUTHORITY AND THE BIO-**  
6 **SHIELD SPECIAL RESERVE FUND.**

7 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section  
8 319F–2(g)(1) of the Public Health Service Act (42 U.S.C.  
9 247d–6b(g)(1)) is amended—

10 (1) by striking “\$2,800,000,000 for the period  
11 of fiscal years 2014 through 2018” and inserting  
12 “\$7,100,000,000 for the period of fiscal years 2019  
13 through 2028, to remain available until expended”;  
14 and

15 (2) by striking the second sentence.

16 (b) THE BIOMEDICAL ADVANCED RESEARCH AND  
17 DEVELOPMENT AUTHORITY.—Subsection (f)(2) of section  
18 319L of the Public Health Service Act (42 U.S.C. 247d–  
19 7e), as redesignated by section 404, is amended by strik-  
20 ing “\$415,000,000 for each of fiscal years 2014 through  
21 2018” and inserting “\$611,700,000 for each of fiscal  
22 years 2019 through 2023”.

1 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**  
2 **BIOTIC RESISTANCE.**

3 Part B of title III of the Public Health Service Act  
4 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
5 tion 319E the following:

6 **“SEC. 319E-1. ADVISORY COUNCIL ON COMBATING ANTI-**  
7 **BIOTIC-RESISTANT BACTERIA.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) ACTION PLAN.—The term ‘Action Plan’  
10 means the Action Plan described in section  
11 319E(a)(1).

12 “(2) ADVISORY COUNCIL.—The term ‘Advisory  
13 Council’ means the Presidential Advisory Council on  
14 Combating Antibiotic-Resistant Bacteria established  
15 by Executive Order 13676 of September 18, 2014  
16 (79 Fed. Reg. 56931; relating to combating anti-  
17 biotic-resistant bacteria).

18 “(3) NATIONAL STRATEGY.—The term ‘Na-  
19 tional Strategy’ means the National Strategy for  
20 Combating Antibiotic-Resistant Bacteria issued by  
21 the White House in September 2014, and any subse-  
22 quent update to such strategy or a successor strat-  
23 egy.

24 “(b) ADVISORY COUNCIL.—The Advisory Council  
25 shall provide advice, information, and recommendations to  
26 the Secretary regarding programs and policies intended to



1 support and evaluate the implementation of Executive  
2 Order 13676 of September 18, 2014 (79 Fed. Reg. 56931;  
3 relating to combating antibiotic-resistant bacteria), includ-  
4 ing the National Strategy, and the Action Plan.

5 “(c) MEETINGS AND DUTIES.—

6 “(1) MEETINGS.—The Advisory Council shall  
7 meet as the Chair determines appropriate but not  
8 less than twice per year, and, to the extent prac-  
9 ticable, in conjunction with meetings of the task  
10 force described in section 319E.

11 “(2) RECOMMENDATIONS.—The Advisory Coun-  
12 cil shall make recommendations to the Secretary, in  
13 consultation with the Secretary of Agriculture and  
14 the Secretary of Defense, regarding programs and  
15 policies intended to—

16 “(A) preserve the effectiveness of anti-  
17 biotics by optimizing their use;

18 “(B) advance research to develop improved  
19 methods for combating antibiotic resistance and  
20 conducting antimicrobial stewardship, as de-  
21 fined in section 319E(h)(3);

22 “(C) strengthen surveillance of antibiotic-  
23 resistant bacterial infections;

24 “(D) prevent the transmission of anti-  
25 biotic-resistant bacterial infections;

1           “(E) advance the development of rapid  
2 point-of-care and agricultural diagnostics;

3           “(F) further research on new treatments  
4 for bacterial infections;

5           “(G) develop alternatives to antibiotics for  
6 animal health purposes;

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

11           “(I) improve international coordination of  
12 efforts to combat antibiotic resistance.

13           “(3) COORDINATION.—The Advisory Council  
14 shall, to the greatest extent practicable, coordinate  
15 activities carried out by the Council with the Anti-  
16 microbial Resistance Task Force established under  
17 section 319E(a) (commonly referred to as the ‘Com-  
18 battling Antibiotic-Resistant Bacteria Task Force’).”.

19 **TITLE VI—ADVANCING TECH-**  
20 **NOLOGIES FOR MEDICAL**  
21 **COUNTERMEASURES**

22 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

23           Section 319L(e)(4)(D)(iii) of the Public Health Serv-  
24 ice Act (42 U.S.C. 247d–7e(e)(4)(D)(iii)) is amended by  
25 striking “and platform technologies” and inserting “plat-

1 form technologies, technologies to administer counter-  
2 measures, and technologies to improve storage and trans-  
3 portation of countermeasures”.

4 **SEC. 602. UPDATING DEFINITIONS OF OTHER TRANS-**  
5 **ACTIONS.**

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

8 (1) in subsection (a)(3), by striking “, such as”  
9 and all that follows through “Code”;

10 (2) in subsection (c)(5)(A)—

11 (A) in clause (i), by striking “under this  
12 subsection” and all that follows through “Code”  
13 and inserting “(as defined in subsection (a)(3))  
14 under this subsection”; and

15 (B) in clause (ii)—

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

18 “(I) IN GENERAL.—To the max-  
19 imum extent practicable, competitive  
20 procedures shall be used when enter-  
21 ing into transactions to carry out  
22 projects under this subsection.”; and

23 (ii) in subclause (II)—

24 (I) by striking “\$20,000,000”  
25 and inserting “\$100,000,000”;

1 (II) by striking “senior procure-  
2 ment executive for the Department  
3 (as designated for the purpose of sec-  
4 tion 16(c) of the Office of Federal  
5 Procurement Policy Act (41 U.S.C.  
6 414(c))” and inserting “Assistant  
7 Secretary for Financial Resources”;  
8 and

9 (III) by striking “senior procure-  
10 ment executive under” and inserting  
11 “Assistant Secretary for Financial Re-  
12 sources under”.

13 **SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.**

14 (a) IN GENERAL.—The purpose of this section (in-  
15 cluding section 565B of the Federal Food, Drug, and Cos-  
16 metic Act, as added by subsection (b)) is to support and  
17 advance the development or manufacture of security coun-  
18 termeasures, qualified countermeasures, and qualified  
19 pandemic or epidemic products by facilitating and encour-  
20 aging submission of data and information to support such  
21 products to medical countermeasure master files, and  
22 through clarifying the authority to cross-reference to data  
23 and information previously submitted to the Secretary of  
24 Health and Human Services (referred to in this section  
25 as the “Secretary”).

1 (b) MEDICAL COUNTERMEASURE MASTER FILES.—  
2 Chapter V of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 351 et seq.) is amended by inserting after sec-  
4 tion 565A the following:

5 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

6 “(a) APPLICABILITY OF REFERENCE.—

7 “(1) IN GENERAL.—A person may submit data  
8 and information in a medical countermeasure master  
9 file to the Secretary with the intent to reference, or  
10 to authorize, in writing, another person to reference,  
11 such data or information within a medical counter-  
12 measure master file to support a medical counter-  
13 measure submission (including a supplement or  
14 amendment to any such submission), without requir-  
15 ing the master file holder to disclose the data and  
16 information to any such persons authorized to ref-  
17 erence the master file. Such data and information  
18 shall be available for reference by the master file  
19 holder or by a person authorized by the master file  
20 holder, in accordance with applicable privacy and  
21 confidentiality protocols and regulations.

22 “(2) REFERENCE OF CERTAIN MASTER  
23 FILES.—In the case that data or information within  
24 a medical countermeasure master file is used only to  
25 support the conditional approval of an application

1 filed under section 571, such master file may be re-  
2 lied upon to help support the effectiveness of a prod-  
3 uct that is the subject of a subsequent medical coun-  
4 termeasure submission only if such application is  
5 supplemented by additional data or information to  
6 support review and approval in a manner consistent  
7 with the standards applicable to such review and ap-  
8 proval for such countermeasure, qualified counter-  
9 measure, or qualified pandemic or epidemic product.

10 “(b) MEDICAL COUNTERMEASURE MASTER FILE  
11 CONTENT.—

12 “(1) IN GENERAL.—A master file under this  
13 section may include data or information to sup-  
14 port—

15 “(A) the development of medical counter-  
16 measure submissions to support the approval,  
17 licensure, classification, clearance, conditional  
18 approval, or authorization of one or more secu-  
19 rity countermeasures, qualified counter-  
20 measures, or qualified pandemic or epidemic  
21 products; and

22 “(B) the manufacture of security counter-  
23 measures, qualified countermeasures, or quali-  
24 fied pandemic or epidemic products.

1           “(2) REQUIRED UPDATES.—The Secretary may  
2           require, as appropriate, that the master file holder  
3           ensure that the contents of such master file are up-  
4           dated during the time such master file is referenced  
5           for a medical countermeasure submission.

6           “(c) SPONSOR REFERENCE.—

7           “(1) IN GENERAL.—Each incorporation of data  
8           or information within a medical countermeasure  
9           master file shall describe the incorporated material  
10          in a manner in which the Secretary determines ap-  
11          propriate and that permits the review of such infor-  
12          mation within such master file without necessitating  
13          re-submission of such data or information. Master  
14          files shall be submitted in an electronic format in ac-  
15          cordance with sections 512(b)(4), 571(a)(4), and  
16          745A, as applicable, and as specified in applicable  
17          guidance.

18          “(2) REFERENCE BY A MASTER FILE HOLD-  
19          ER.—A master file holder that is the sponsor of a  
20          medical countermeasure submission shall notify the  
21          Secretary in writing of the intent to reference the  
22          medical countermeasure master file as a part of the  
23          submission.

24          “(3) REFERENCE BY AN AUTHORIZED PER-  
25          SON.—A person submitting an application for review

1       may, where the Secretary determines appropriate,  
2       incorporate by reference all or part of the contents  
3       of a medical countermeasure master file, if the mas-  
4       ter file holder authorizes the incorporation in writ-  
5       ing.

6       “(d) ACKNOWLEDGEMENT OF THE RELIANCE UPON  
7       A MASTER FILE BY THE SECRETARY.—

8               “(1) IN GENERAL.—The Secretary shall provide  
9       the master file holder with a written notification in-  
10       dicating that the Secretary has reviewed and relied  
11       upon specified data or information within a master  
12       file and the purposes for which such data or infor-  
13       mation was incorporated by reference if the Sec-  
14       retary has reviewed and relied upon such specified  
15       data or information to support the approval, classi-  
16       fication, conditional approval, clearance, licensure, or  
17       authorization of a security countermeasure, qualified  
18       countermeasure, or qualified pandemic or epidemic  
19       product. The Secretary may rely upon the data and  
20       information within the medical countermeasure mas-  
21       ter file for which such written notification was pro-  
22       vided in additional applications, as applicable and  
23       appropriate and upon the request of the master file  
24       holder so notified in writing or by an authorized per-  
25       son of such holder.



1           “(2) CERTAIN APPLICATIONS.—If the Secretary  
2           has reviewed and relied upon specified data or infor-  
3           mation within a medical countermeasure master file  
4           to support the conditional approval of an application  
5           under section 571 to subsequently support the ap-  
6           proval, clearance, licensure, or authorization of a se-  
7           curity countermeasure, qualified countermeasure, or  
8           qualified pandemic or epidemic product, the Sec-  
9           retary shall provide a brief written description to the  
10          master file holder regarding the elements of the ap-  
11          plication fulfilled by the data or information within  
12          the master file and how such data or information  
13          contained in such application meets the standards of  
14          evidence under subsection (c) or (d) of section 505,  
15          subsection (d) of section 512, or section 351 of the  
16          Public Health Service Act (as applicable) unless  
17          such disclosure includes any trade secret or con-  
18          fidential commercial information.

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

21                 “(1) limit the authority of the Secretary to ap-  
22                 prove, license, clear, conditionally approve, or au-  
23                 thorize drugs, biological products, or devices pursu-  
24                 ant to, as applicable, this Act or section 351 of the  
25                 Public Health Service Act (as such applicable Act is

1 in effect on the day before the date of enactment of  
2 the Pandemic and All-Hazards Preparedness and  
3 Advancing Innovation Act of 2018), including the  
4 standards of evidence, and applicable conditions, for  
5 approval under the applicable Act;

6 “(2) alter the standards of evidence with re-  
7 spect to approval, licensure, or clearance, as applica-  
8 ble, of drugs, biological products, or devices under  
9 this Act or section 351 of the Public Health Service  
10 Act, including, as applicable, the substantial evi-  
11 dence standards under sections 505(d) and 512(d)  
12 or this Act and section 351(a) of the Public Health  
13 Service Act; or

14 “(3) alter the authority of the Secretary under  
15 this Act or the Public Health Service Act to deter-  
16 mine the types of data or information previously  
17 submitted by a sponsor or any other person that  
18 may be incorporated by reference in an application,  
19 request, or notification for a drug, biological prod-  
20 uct, or device submitted under sections 505(i),  
21 505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564,  
22 571, 520(g), 515(c), 513(f)(2), or 510(k) of this  
23 Act, or subsection (a) or (k) of section 351 of the  
24 Public Health Service Act, including a supplement

1 or amendment to any such submission, and the re-  
2 quirements associated with such reference.

3 “(f) DEFINITIONS.—In this section:

4 “(1) The term ‘master file holder’ means a per-  
5 son who submits data and information to the Sec-  
6 retary with the intent to reference or authorize an-  
7 other person to reference such data or information  
8 to support a medical countermeasure submission, as  
9 described in subsection (a).

10 “(2) The term ‘medical countermeasure submis-  
11 sion’ means an investigational new drug application  
12 under section 505(i), a new drug application under  
13 section 505(b), or an abbreviated new drug applica-  
14 tion under section 505(j) of this Act, a biological  
15 product license application under section 351(a) of  
16 the Public Health Service Act or a biosimilar biologi-  
17 cal product license application under section 351(k)  
18 of the Public Health Service Act, a new animal drug  
19 application under section 512(b)(1) or abbreviated  
20 new animal drug application under section  
21 512(b)(2), an application for conditional approval of  
22 a new animal drug under section 571, an investiga-  
23 tional device application under section 520(g), an  
24 application with respect to a device under section  
25 515(c), a request for classification of a device under

1 section 513(f)(2), a notification with respect to a de-  
2 vice under section 510(k), or a request for an emer-  
3 gency use authorization under section 564 to sup-  
4 port—

5 “(A) the approval, licensure, classification,  
6 clearance, conditional approval, or authorization  
7 of a security countermeasure, qualified counter-  
8 measure, or qualified pandemic or epidemic  
9 product; or

10 “(B) a new indication to an approved secu-  
11 rity countermeasure, qualified countermeasure,  
12 or qualified pandemic or epidemic product.

13 “(3) The terms ‘qualified countermeasure’, ‘se-  
14 curity countermeasure’, and ‘qualified pandemic or  
15 epidemic product’ have the meanings given such  
16 terms in sections 319F–1, 319F–2, and 319F–3, re-  
17 spectively, of the Public Health Service Act.”.

18 (c) **STAKEHOLDER INPUT.**—Not later than 18  
19 months after the date of enactment of this Act, the Sec-  
20 retary, acting through the Commissioner of Food and  
21 Drugs and in consultation with the Assistant Secretary  
22 for Preparedness and Response, shall solicit input from  
23 stakeholders, including stakeholders developing security  
24 countermeasures, qualified countermeasures, or qualified  
25 pandemic or epidemic products, and stakeholders devel-

1 oping technologies to assist in the development of such  
2 countermeasures with respect to how the Food and Drug  
3 Administration can advance the use of tools and tech-  
4 nologies to support and advance the development or manu-  
5 facture of security countermeasures, qualified counter-  
6 measures, and qualified pandemic or epidemic products,  
7 including through reliance on cross-referenced data and  
8 information contained within master files and submissions  
9 previously submitted to the Secretary as set forth in sec-  
10 tion 565B of the Federal Food, Drug, and Cosmetic Act,  
11 as added by subsection (b).

12 (d) GUIDANCE.—Not later than 2 years after the  
13 date of enactment of this Act, the Secretary, acting  
14 through the Commissioner of Food and Drugs, shall pub-  
15 lish draft guidance about how reliance on cross-referenced  
16 data and information contained within master files under  
17 section 565B of the Federal Food, Drug, and Cosmetic  
18 Act, as added by subsection (b) or submissions otherwise  
19 submitted to the Secretary may be used for specific tools  
20 or technologies (including platform technologies) that have  
21 the potential to support and advance the development or  
22 manufacture of security countermeasures, qualified coun-  
23 termeasures, and qualified pandemic or epidemic products.  
24 The Secretary, acting through the Commissioner of Food

1 and Drugs, shall publish the final guidance not later than  
2 3 years after the enactment of this Act.

3 **SEC. 604. ANIMAL RULE REPORT.**

4 (a) STUDY.—The Comptroller General of the United  
5 States shall conduct a study on the application of the re-  
6 quirements under subsections (c) and (d) of section 565  
7 of the of the Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 360bbb–4) (referred to in this section as the “ani-  
9 mal rule”) as a component of medical countermeasure ad-  
10 vanced development under the Biomedical Advanced Re-  
11 search and Development Authority and regulatory review  
12 by the Food and Drug Administration. In conducting such  
13 study, the Comptroller General shall examine the fol-  
14 lowing:

15 (1) The extent to which advanced development  
16 and review of a medical countermeasure are coordi-  
17 nated between the Biomedical Advanced Research  
18 and Development Authority and the Food and Drug  
19 Administration, including activities that facilitate  
20 appropriate and efficient design of studies to sup-  
21 port approval, licensure, and authorization under the  
22 animal rule, consistent with the recommendations in  
23 the animal rule guidance, issued pursuant to section  
24 565(c) of the Federal Food Drug and Cosmetic Act  
25 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-

1       velopment Under the Animal Rule: Guidance for In-  
2       dustry” (issued in October 2015), to resolve discrep-  
3       ancies in the design of adequate and well-controlled  
4       efficacy studies conducted in animal models related  
5       to the provision of substantial evidence of effective-  
6       ness for the product approved, licensed, or author-  
7       ized under the animal rule.

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

11              (3) The flexibility pursuant to the animal rule  
12      to address variations in countermeasure development  
13      and review processes, including the extent to which  
14      qualified animal models are adopted and used within  
15      the Food and Drug Administration in regulatory de-  
16      cisionmaking with respect to medical counter-  
17      measures.

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

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

4 (1) the Federal agencies responsible for advanc-  
5 ing, reviewing, and procuring medical counter-  
6 measures, including the Office of the Assistant Sec-  
7 retary for Preparedness and Response, the Bio-  
8 medical Advanced Research and Development Au-  
9 thority, the Food and Drug Administration, and the  
10 Department of Defense;

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

15 (3) other biodefense stakeholders, as applicable.

16 (c) REPORT.—Not later than 3 years after the date  
17 of enactment of this Act, the Comptroller General of the  
18 United States shall submit to the Committee on Health,  
19 Education, Labor, and Pensions of the Senate and the  
20 Committee on Energy and Commerce of the House of  
21 Representatives a report containing the results of the  
22 study conducted under subsection (a) and recommenda-  
23 tions to improve the application and consistency of the re-  
24 quirements under subsections (c) and (d) of section 565  
25 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.



1 360bbb-4) to support and expedite the research and devel-  
2 opment of medical countermeasures, as applicable.

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

8 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**  
9 **NEERING TECHNOLOGIES AND THEIR POTEN-**  
10 **TIAL ROLE IN NATIONAL SECURITY.**

11 (a) MEETING.—

12 (1) IN GENERAL.—Not later than 1 year after  
13 the date of enactment of this Act, the Secretary of  
14 Health and Human Services (referred to in this sec-  
15 tion as the “Secretary”) shall convene a meeting to  
16 discuss the potential role advancements in genomic  
17 engineering technologies (including genome editing  
18 technologies) may have in advancing national health  
19 security. Such meeting shall be held in a manner  
20 that does not compromise national security.

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

23 (A) shall include—

24 (i) representatives from the Office of  
25 the Assistant Secretary for Preparedness

1 and Response, the National Institutes of  
2 Health, the Centers for Disease Control  
3 and Prevention, and the Food and Drug  
4 Administration; and

5 (ii) representatives from academic,  
6 private, and nonprofit entities with exper-  
7 tise in genome engineering technologies,  
8 biopharmaceuticals, medicine, or bio-  
9 defense, and other relevant stakeholders;  
10 and

11 (B) may include—

12 (i) other representatives from the De-  
13 partment of Health and Human Services,  
14 as the Secretary determines appropriate;  
15 and

16 (ii) representatives from the Depart-  
17 ment of Homeland Security, the Depart-  
18 ment of Defense, the Department of Agri-  
19 culture, and other departments, as the Sec-  
20 retary may request for the meeting.

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

23 (A) the current state of the science of  
24 genomic engineering technologies related to na-  
25 tional health security, including—

1 (i) medical countermeasure develop-  
2 ment, including potential efficiencies in the  
3 development pathway and detection tech-  
4 nologies; and

5 (ii) the international and domestic  
6 regulation of products utilizing genome ed-  
7 iting technologies; and

8 (B) national security implications, includ-  
9 ing—

10 (i) capabilities of the United States to  
11 leverage genomic engineering technologies  
12 as a part of the medical countermeasure  
13 enterprise, including current applicable re-  
14 search, development, and application ef-  
15 forts underway within the Department of  
16 Defense;

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

21 (iii) security measures to monitor and  
22 assess the potential threat that may result  
23 from utilization of genomic engineering  
24 technologies and related technologies for

1           the purpose of compromising national  
2           health security.

3       (b) REPORT.—Not later than 270 days after the  
4 meeting described in subsection (a) is held, the Assistant  
5 Secretary for Preparedness and Response shall issue a re-  
6 port to the congressional committees of jurisdiction on the  
7 topics discussed at such meeting, and provide rec-  
8 ommendations, as applicable, to utilize innovations in  
9 genomic engineering (including genome editing) and re-  
10 lated technologies as a part of preparedness and response  
11 activities to advance national health security. Such report  
12 shall be issued in a manner that does not compromise na-  
13 tional security.

14 **SEC. 606. REPORT ON VACCINES DEVELOPMENT.**

15       Not later than one year after the date of the enact-  
16 ment of this Act, the Secretary of Health and Human  
17 Services shall submit to the Committee on Health, Edu-  
18 cation, Labor, and Pensions of the Senate and the Com-  
19 mittee on Energy and Commerce of the House of Rep-  
20 resentatives a report describing efforts and activities to  
21 coordinate with other countries and international partners  
22 during recent public health emergencies with respect to  
23 the research and advanced research on, and development  
24 of, qualified pandemic or epidemic products (as defined  
25 in section 319F–3 of the Public Health Service Act (42

1 U.S.C. 247d–6d)). Such report may include information  
2 regarding relevant work carried out under section  
3 319L(c)(5)(E) of the Public Health Service Act (42  
4 U.S.C. 247d–7e(c)(5)(E)), through public-private partner-  
5 ships, and through collaborations with other countries to  
6 assist with or expedite the research and development of  
7 qualified pandemic or epidemic products. Such report shall  
8 not include information that may compromise national se-  
9 curity.

10 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**  
11 **SAFETY AND HEALTH.**

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

16 (1) in subsection (a)(1)(B)—

17 (A) by inserting “including programs to  
18 address emerging infectious mosquito-borne dis-  
19 eases,” after “subdivisions for control pro-  
20 grams,”; and

21 (B) by inserting “or improving existing  
22 control programs” before the period at the end;

23 (2) in subsection (b)—

24 (A) in paragraph (1), by inserting “, in-  
25 cluding improvement,” after “operation”;

1 (B) in paragraph (2)—

2 (i) in subparagraph (A)—

3 (I) in clause (ii), by striking “or”  
4 at the end;

5 (II) in clause (iii), by striking the  
6 semicolon at the end and inserting “,  
7 including an emerging infectious mos-  
8 quito-borne disease that presents a se-  
9 rious public health threat; or”; and

10 (III) by adding at the end the  
11 following:

12 “(iv) a public health emergency due to  
13 the incidence or prevalence of a mosquito-  
14 borne disease that presents a serious pub-  
15 lic health threat;”; and

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

18 “(D)(i) is located in a State that has re-  
19 ceived a grant under subsection (a); or

20 “(ii) that demonstrates to the Secretary  
21 that the control program is consistent with ex-  
22 isting State mosquito control plans or policies,  
23 or other applicable State preparedness plans.”;

24 (C) in paragraph (4)(C), by striking “that  
25 extraordinary” and all that follows through the

1 period at the end and inserting the following:

2 “that—

3 “(i) extraordinary economic conditions  
4 in the political subdivision or consortium of  
5 political subdivisions involved justify the  
6 waiver; or

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

11 “(I) the size or density of the po-  
12 tentially impacted human population;

13 “(II) the size or density of a  
14 mosquito population that requires  
15 heightened control; or

16 “(III) the severity of the mos-  
17 quito-borne disease, such that ex-  
18 pected serious adverse health out-  
19 comes for the human population jus-  
20 tify the waiver.”; and

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

23 “(6) NUMBER OF GRANTS.—A political subdivi-  
24 sion or a consortium of political subdivisions may

1 not receive more than one grant under paragraph  
2 (1).”; and

3 (3) in subsection (f)—

4 (A) in paragraph (1) by striking “for fiscal  
5 year 2003, and such sums as may be necessary  
6 for each of fiscal years 2004 through 2007”  
7 and inserting “for each of fiscal years 2019  
8 through 2023”;

9 (B) in paragraph (2), by striking “the  
10 Public Health Security and Bioterrorism Pre-  
11 paredness and Response Act of 2002” and in-  
12 serting “this Act and other medical and public  
13 health preparedness and response laws”; and

14 (C) in paragraph (3)—

15 (i) in the heading, by striking “2004”  
16 and inserting “2019”; and

17 (ii) by striking “2004” and inserting  
18 “2019”.

19 (b) EPIDEMIOLOGY-LABORATORY CAPACITY  
20 GRANTS.—Section 2821 of the Public Health Service Act  
21 (42 U.S.C. 300hh–31) is amended—

22 (1) in subsection (a)(1), by inserting “, includ-  
23 ing mosquito and other vector-borne diseases,” after  
24 “infectious diseases”; and



1 (2) in subsection (b), by striking “2010 through  
2 2013” and inserting “2019 through 2023”.

## 3 **TITLE VII—MISCELLANEOUS** 4 **PROVISIONS**

### 5 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

6 (a) VACCINE TRACKING AND DISTRIBUTION.—Sec-  
7 tion 319A(e) of the Public Health Service Act (42 U.S.C.  
8 247d–1(e)) is amended by striking “2014 through 2018”  
9 and inserting “2019 through 2023”.

10 (b) TEMPORARY REASSIGNMENT.—Section 319(e)(8)  
11 of the Public Health Service Act (42 U.S.C. 247d(e)(8))  
12 is amended by striking “2018” and inserting “2023”.

13 (c) STRATEGIC INNOVATION PARTNER.—Section  
14 319L(c)(4)(E)(ix) of the Public Health Service Act (42  
15 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking  
16 “2022” and inserting “2023”.

17 (d) LIMITED ANTITRUST EXEMPTION.—

18 (1) IN GENERAL.—Section 405 of the Pandemic  
19 and All-Hazards Preparedness Act (42 U.S.C.  
20 247d–6a note) is amended—

21 (A) by redesignating such section as sec-  
22 tion 319L–1;

23 (B) by transferring such section to the  
24 Public Health Service Act (42 U.S.C. 201 et

1 seq.), to appear after section 319L of such Act  
2 (42 U.S.C. 247d–7e);

3 (C) in subsection (a)(1)(A)—

4 (i) by striking “Secretary of Health  
5 and Human Services (referred to in this  
6 subsection as the ‘Secretary’)” and insert-  
7 ing “Secretary”;

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

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

14 (iv) by striking “of the Public Health  
15 Service Act (42 U.S.C. 247d–6d)”;

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

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

22 (e) INAPPLICABILITY OF CERTAIN PROVISIONS.—  
23 Subsection (g)(1) of section 319L of the Public Health  
24 Service Act (42 U.S.C. 247d–7e), as redesignated by sec-  
25 tion 404, is amended—

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

3           “(A) NON-DISCLOSURE OF INFORMA-  
4 TION.—

5           “(i) IN GENERAL.—Information de-  
6 scribed in clause (ii) shall be deemed to be  
7 information described in section 552(b)(3)  
8 of title 5, United States Code.

9           “(ii) INFORMATION DESCRIBED.—The  
10 information described in this clause is in-  
11 formation relevant to programs of the De-  
12 partment of Health and Human Services  
13 that could compromise national security  
14 and reveal significant and not otherwise  
15 publicly known vulnerabilities of existing  
16 medical or public health defenses against  
17 chemical, biological, radiological, or nuclear  
18 threats, and is comprised of—

19           “(I) specific technical data or sci-  
20 entific information that is created or  
21 obtained during the countermeasure  
22 and product advanced research and  
23 development carried out under sub-  
24 section (c);

1                   “(II) information pertaining to  
2                   the location security, personnel, and  
3                   research materials and methods of  
4                   high-containment laboratories con-  
5                   ducting research with select agents,  
6                   toxins, or other agents with a material  
7                   threat determination under section  
8                   319F–2(c)(2); or

9                   “(III) security and vulnerability  
10                  assessments.”;

11                  (2) by redesignating subparagraph (C) as sub-  
12                  paragraph (D);

13                  (3) by inserting after subparagraph (B) the fol-  
14                  lowing:

15                  “(C) REPORTING.—One year after the  
16                  date of enactment of the Pandemic and All-  
17                  Hazards Preparedness and Advancing Innova-  
18                  tion Act of 2018, and annually thereafter, the  
19                  Secretary shall report to the Committee on  
20                  Health, Education, Labor, and Pensions of the  
21                  Senate and the Committee on Energy and Com-  
22                  merce of the House of Representatives on the  
23                  number of instances in which the Secretary has  
24                  used the authority under this subsection to  
25                  withhold information from disclosure, as well as

1 the nature of any request under section 552 of  
2 title 5, United States Code that was denied  
3 using such authority.”; and

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

6 **SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.**

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

10 “(d) DISCLOSURES.—No Federal agency may dis-  
11 close under section 552 of title 5, United States Code any  
12 information identifying the location at which materials in  
13 the stockpile described in subsection (a) are stored, or  
14 other information regarding the contents or deployment  
15 capability of the stockpile that could compromise national  
16 security.”.

17 **SEC. 703. CYBERSECURITY.**

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

20 (1) STRATEGY.—Not later than 18 months  
21 after the date of enactment of this Act, the Sec-  
22 retary of Health and Human Services (referred to in  
23 this section as the “Secretary”) shall prepare and  
24 submit to the relevant committees of Congress a  
25 strategy for public health preparedness and response

1 to address cybersecurity threats (as defined in sec-  
2 tion 102 of Cybersecurity Information Sharing Act  
3 of 2015 (6 U.S.C. 1501)) that present a threat to  
4 national health security. Such strategy shall in-  
5 clude—

6 (A) identifying the duties, functions, and  
7 preparedness goals for which the Secretary is  
8 responsible in order to prepare for and respond  
9 to such cybersecurity threats, including metrics  
10 by which to measure success in meeting pre-  
11 paredness goals;

12 (B) identifying gaps in public health capa-  
13 bilities to achieve such preparedness goals; and

14 (C) strategies to address identified gaps  
15 and strengthen public health emergency pre-  
16 paredness and response capabilities to address  
17 such cybersecurity threats.

18 (2) PROTECTION OF NATIONAL SECURITY.—

19 The Secretary shall make such strategy available to  
20 the Committee on Health, Education, Labor, and  
21 Pensions of the Senate, the Committee on Energy  
22 and Commerce of the House of Representatives, and  
23 other congressional committees of jurisdiction, in a  
24 manner that does not compromise national security.

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

6 “(D) POLICY COORDINATION AND STRA-  
7 TEGIC DIRECTION.—Provide integrated policy  
8 coordination and strategic direction, before,  
9 during, and following public health emergencies,  
10 with respect to all matters related to Federal  
11 public health and medical preparedness and  
12 execution and deployment of the Federal re-  
13 sponse for public health emergencies and inci-  
14 dents covered by the National Response Plan  
15 described in section 504(a)(6) of the Homeland  
16 Security Act of 2002 (6 U.S.C. 314(a)(6)), or  
17 any successor plan; and such Federal responses  
18 covered by the National Cybersecurity Incident  
19 Response Plan developed under section 228(c)  
20 of the Homeland Security Act of 2002 (6  
21 U.S.C. 149(c)), including public health emer-  
22 gencies or incidents related to cybersecurity  
23 threats that present a threat to national health  
24 security.”.

1 **SEC. 704. TECHNICAL AMENDMENTS.**

2 (a) PUBLIC HEALTH SERVICE ACT.—Title III of the  
3 Public Health Service Act (42 U.S.C. 241 et seq.) is  
4 amended—

5 (1) in paragraphs (1) and (5) of section 319F–  
6 1(a) (42 U.S.C. 247d–6a(a)), by striking “section  
7 319F(h)” each place such term appears and insert-  
8 ing “section 319F(e)”; and

9 (2) in section 319K(a) (42 U.S.C. 247d–7d(a)),  
10 by striking “section 319F(h)(4)” and inserting “sec-  
11 tion 319F(e)(4)”.

12 (b) PUBLIC HEALTH SECURITY GRANTS.—Section  
13 319C–1(b)(2) of the Public Health Service Act (42 U.S.C.  
14 247d–3a(b)(2)) is amended—

15 (1) in subparagraph (C), by striking “individ-  
16 uals,” and inserting “individuals,”; and

17 (2) in subparagraph (F), by striking “make sat-  
18 isfactory annual improvement and describe” and in-  
19 serting “makes satisfactory annual improvement and  
20 describes”.

21 (c) EMERGENCY USE INSTRUCTIONS.—Subpara-  
22 graph (A) of section 564A(e)(2) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is  
24 amended by striking “subsection (a)(1)(C)(i)” and insert-  
25 ing “subsection (a)(1)(C)”.



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

4 (1) in subparagraph (B), by inserting a comma  
5 after “505”; and

6 (2) in subparagraph (C), by inserting “or sec-  
7 tion 564A” before the period at the end.

8 (e) TRANSPARENCY.—Section 507(c)(3) of the Fed-  
9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 357(c)(3))  
10 is amended—

11 (1) by striking “Nothing in” and inserting the  
12 following:

13 “(A) IN GENERAL.—Nothing in”;

14 (2) by striking “disclose any” and inserting  
15 “disclose or direct—

16 “(i) any”;

17 (3) by striking the period and inserting “; or”;

18 and

19 (4) by adding at the end the following:

20 “(ii) in the case of a drug develop-  
21 ment tool that may be used to support the  
22 development of a qualified countermeasure,  
23 security countermeasure, or qualified pan-  
24 demic or epidemic product, as defined in  
25 sections 319F–1, 319F–2, and 319F–3,

1                   respectively, of the Public Health Service  
2                   Act, any information that the Secretary  
3                   determines has a significant potential to  
4                   affect national security.

5                   “(B) PUBLIC ACKNOWLEDGMENT.—In the  
6                   case that the Secretary, pursuant to subpara-  
7                   graph (A), does not make information publicly  
8                   available, the Secretary shall provide on the  
9                   internet website of the Food and Drug Admin-  
10                  istration an acknowledgement of the informa-  
11                  tion that has not been disclosed, pursuant to  
12                  subparagraph (A).”.

13 **SEC. 705. FORMAL STRATEGY RELATING TO CHILDREN**  
14                   **SEPARATED FROM PARENTS AND GUARD-**  
15                   **IANAS AS A RESULT OF ZERO TOLERANCE POL-**  
16                   **ICY.**

17                  Not later than 14 days after the date of enactment  
18                  of this Act, the Assistant Secretary for Preparedness and  
19                  Response and the Assistant Secretary for the Administra-  
20                  tion on Children and Families shall submit to the Com-  
21                  mittee on Energy and Commerce of the House of Rep-  
22                  resentatives a formal strategy to reunify with their parent  
23                  or guardian, if the parent or guardian chooses such reuni-  
24                  fication, each child who—

1 (1) as a result of the initiative announced on  
2 April 7, 2018, and due to prosecution under section  
3 1325(a) of title 8, United States Code;

4 (2) was separated from their parent or guard-  
5 ian and placed into a facility funded by the Depart-  
6 ment of Health and Human Services; and

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

9 **SEC. 706. REPORTING RELATING TO CHILDREN SEPARATED**  
10 **FROM PARENTS AND GUARDIANS AS A RE-**  
11 **SULT OF ZERO TOLERANCE POLICY.**

12 Beginning on the date of enactment of this Act, the  
13 Assistant Secretary for Preparedness and Response shall  
14 submit to the Committee on Energy and Commerce of the  
15 House of Representatives weekly reports on the status and  
16 welfare of the children who, as a result of the “zero toler-  
17 ance” policy, were separated from their parent or guard-  
18 ian and are awaiting reunification with their parent or  
19 guardian, as well as the number of such children in facili-  
20 ties funded by the Department of Health and Human  
21 Services.

22 **SEC. 707. TECHNICAL CORRECTION.**

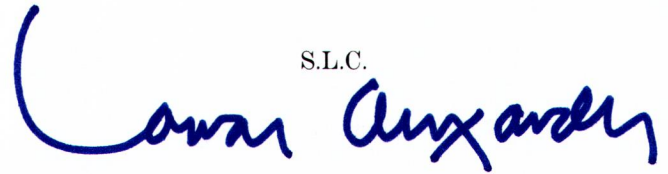
23 Section 801(e)(4)(E)(iii) of the Federal Food, Drug,  
24 and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amend-  
25 ed by striking “subparagraph” both places it appears in

1 subclause (I) and subclause (II) and inserting “para-  
2 graph”.

3 **SEC. 708. SAVINGS CLAUSE.**

4       Nothing in this Act shall be construed as reducing  
5 or limiting the authorities vested in any other Federal  
6 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.”.



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:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

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

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

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

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

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

#### TITLE III—REACHING ALL COMMUNITIES

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

#### TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

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

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

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

#### TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
- Sec. 602. Medical countermeasure master files.
- Sec. 603. Priority zoonotic animal drugs.
- Sec. 604. Animal rule report.
- Sec. 605. Review of the benefits of genomic engineering technologies and their potential role in national security.

#### TITLE VII—MISCELLANEOUS PROVISIONS

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

1 **SEC. 2. REFERENCES IN ACT.**

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

6 **TITLE I—STRENGTHENING THE**  
7 **NATIONAL HEALTH SECURITY**  
8 **STRATEGY**

9 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

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

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by striking “2014” and inserting  
14 “2018”; and

15 (ii) by striking the second sentence  
16 and inserting the following: “Such Na-  
17 tional Health Security Strategy shall de-  
18 scribe potential emergency health security  
19 threats and identify the process for achiev-  
20 ing the preparedness goals described in  
21 subsection (b) to be prepared to identify  
22 and respond to such threats and shall be  
23 consistent with the national preparedness  
24 goal (as described in section 504(a)(19) of  
25 the Homeland Security Act of 2002), the  
26 National Incident Management System (as

1 defined in section 501(7) of such Act), and  
2 the National Response Plan developed pur-  
3 suant to section 504 of such Act, or any  
4 successor plan.”;

5 (B) in paragraph (2), by inserting before  
6 the period at the end of the second sentence the  
7 following: “, and an analysis of any changes to  
8 the evidence-based benchmarks and objective  
9 standards under sections 319C-1 and 319C-2”;  
10 and

11 (C) in paragraph (3)—

12 (i) by striking “2009” and inserting  
13 “2022”;

14 (ii) by inserting “(including gaps in  
15 the environmental health and animal  
16 health workforces, as applicable), describ-  
17 ing the status of such workforce” after  
18 “gaps in such workforce”;

19 (iii) by striking “and identifying strat-  
20 egies” and inserting “identifying strate-  
21 gies”; and

22 (iv) by inserting before the period at  
23 the end “, and identifying current capabili-  
24 ties to meet the requirements of section  
25 2803”; and



1 (2) in subsection (b)—

2 (A) in paragraph (2)—

3 (i) in subparagraph (A), by striking  
4 “and investigation” and inserting “inves-  
5 tigation, and related information tech-  
6 nology activities”;

7 (ii) in subparagraph (B), by striking  
8 “and decontamination” and inserting “de-  
9 contamination, relevant health care serv-  
10 ices and supplies, and transportation and  
11 disposal of medical waste”; and

12 (iii) by adding at the end the fol-  
13 lowing:

14 “(E) Response to environmental hazards.”;

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

18 (C) in paragraph (5), by inserting “and  
19 other applicable compacts” after “Compact”;  
20 and

21 (D) by adding at the end the following:

22 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-  
23 CULTURE.—Improving coordination among Federal,  
24 State, local, tribal, and territorial entities (including  
25 through consultation with the Secretary of Agri-

1 culture) to prevent, detect, and respond to outbreaks  
2 of plant or animal disease (including zoonotic dis-  
3 ease) that could compromise national security result-  
4 ing from a deliberate attack, a naturally occurring  
5 threat, the intentional adulteration of food, or other  
6 public health threats, taking into account inter-  
7 actions between animal health, human health, and  
8 animals' and humans' shared environment as di-  
9 rectly related to public health emergency prepared-  
10 ness and response capabilities, as applicable.

11 “(10) GLOBAL HEALTH SECURITY.—Assessing  
12 current or potential health security threats from  
13 abroad to inform domestic public health prepared-  
14 ness and response capabilities.”.

15 **TITLE II—IMPROVING**  
16 **PREPAREDNESS AND RESPONSE**

17 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**  
18 **PREPAREDNESS AND RESPONSE.**

19 (a) EVALUATING MEASURABLE EVIDENCE-BASED  
20 BENCHMARKS AND OBJECTIVE STANDARDS.—Section  
21 319C–1 (42 U.S.C. 247d–3a) is amended by inserting  
22 after subsection (j) the following:

23 “(k) EVALUATION.—

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

1 All-Hazards Preparedness and Advancing Innovation  
2 Act of 2018 and every 2 years thereafter, the Sec-  
3 retary shall conduct an evaluation of the evidence-  
4 based benchmarks and objective standards required  
5 under subsection (g). Such evaluation shall be sub-  
6 mitted to the congressional committees of jurisdic-  
7 tion together with the National Health Security  
8 Strategy under section 2802, at such time as such  
9 strategy is submitted.

10 “(2) CONTENT.—The evaluation under this  
11 paragraph shall include—

12 “(A) a review of evidence-based bench-  
13 marks and objective standards, and associated  
14 metrics and targets;

15 “(B) a discussion of changes to any evi-  
16 dence-based benchmarks and objective stand-  
17 ards, and the effect of such changes on the abil-  
18 ity to track whether entities are meeting or  
19 making progress toward the goals under this  
20 section and, to the extent practicable, the appli-  
21 cable goals of the National Health Security  
22 Strategy under section 2802;

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

1 by sub-recipients and the effect of such funding  
2 on meeting evidence-based benchmarks and ob-  
3 jective standards; and

4 “(D) recommendations, as applicable and  
5 appropriate, to improve evidence-based bench-  
6 marks and objective standards to more accu-  
7 rately assess the ability of entities receiving  
8 awards under this section to better achieve the  
9 goals under this section and section 2802.”.

10 (b) EVALUATING THE PARTNERSHIP FOR STATE AND  
11 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C-  
12 2(i)(1) (42 U.S.C. 247-3b(i)(1)) is amended by striking  
13 “section 319C-1(g), (i), and (j)” and inserting “section  
14 319C-1(g), (i), (j), and (k)”.

15 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**  
16 **SPONSE PROGRAMS.**

17 (a) COOPERATIVE AGREEMENT APPLICATIONS FOR  
18 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-  
19 RITY.—Section 319C-1 (42 U.S.C. 247d-3a) is amend-  
20 ed—

21 (1) in subsection (a), by inserting “, acting  
22 through the Director of the Centers for Disease  
23 Control and Prevention,” after “the Secretary”; and

24 (2) in subsection (b)(2)(A)—

1 (A) in clause (vi), by inserting “, including  
2 public health agencies with specific expertise  
3 that may be relevant to public health security,  
4 such as environmental health agencies,” after  
5 “stakeholders”;

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

8 (C) by inserting after clause (vi) the fol-  
9 lowing:

10 “(vii) a description of how, as applica-  
11 ble, such entity may integrate information  
12 to account for individuals with behavioral  
13 health needs following a public health  
14 emergency;”.

15 (b) PARTNERSHIP FOR STATE AND REGIONAL HOS-  
16 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—  
17 Section 319C-2 (42 U.S.C. 247d-3b) is amended—

18 (1) in subsection (a)—

19 (A) by inserting “, acting through the As-  
20 sistant Secretary for Preparedness and Re-  
21 sponse,” after “The Secretary”; and

22 (B) by striking “preparedness for public  
23 health emergencies” and inserting “prepared-  
24 ness for, and response to, public health emer-  
25 gencies in accordance with subsection (c)”; and

1 (2) in subsection (b)(1)(A)—

2 (A) in clause (iii), by redesignating sub-  
3 clauses (I) through (III) as items (aa) through  
4 (cc), respectively, and adjusting the margins ac-  
5 cordingly;

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

9 (C) by striking “partnership consisting  
10 of—” and inserting “partnership—

11 “(i) consisting of—”; and

12 (D) by adding at the end the following:

13 “(ii) that may include one or more  
14 emergency medical service organizations or  
15 emergency management organizations;  
16 and”.

17 (e) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-  
18 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A)  
19 (42 U.S.C. 247d–3a(h)(1)(A)) is amended by striking  
20 “\$641,900,000 for fiscal year 2014” and all that follows  
21 through the period at the end and inserting  
22 “\$685,000,000 for each of fiscal years 2019 through 2023  
23 for awards pursuant to paragraph (3) (subject to the au-  
24 thority of the Secretary to make awards pursuant to para-  
25 graphs (4) and (5)).”.

1 (d) PARTNERSHIP FOR STATE AND REGIONAL HOS-  
2 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-  
3 TIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is  
4 amended—

5 (1) by amending paragraph (1) to read as fol-  
6 lows:

7 “(1) IN GENERAL.—

8 “(A) AUTHORIZATION OF APPROPRIA-  
9 TIONS.—For purposes of carrying out this sec-  
10 tion and section 319C–3, in accordance with  
11 subparagraph (B), there is authorized to be ap-  
12 propriated \$385,000,000 for each of fiscal years  
13 2019 through 2023.

14 “(B) RESERVATIONS OF AMOUNTS FOR RE-  
15 GIONAL SYSTEMS.—

16 “(i) IN GENERAL.—Subject to clause  
17 (ii), of the amount appropriated under sub-  
18 paragraph (A) for a fiscal year, the Sec-  
19 retary may reserve up to 5 percent for the  
20 purpose of carrying out section 319C–3.

21 “(ii) RESERVATIONS CONTINGENT ON  
22 CONTINUED APPROPRIATIONS FOR THIS  
23 SECTION.—If for fiscal year 2019 or a sub-  
24 sequent fiscal year, the amount appro-  
25 priated under subparagraph (A) is such

1           that, after application of clause (i), the  
2           amount remaining for the purpose of car-  
3           rying out this section would be less than  
4           the amount available for such purpose for  
5           the previous fiscal year, the amount that  
6           may be reserved under clause (i) shall be  
7           reduced such that the amount remaining  
8           for the purpose of carrying out this section  
9           is not less than the amount available for  
10          such purpose for the previous fiscal year.

11                   “(iii) SUNSET.—The authority to re-  
12                   serve amounts under clause (i) shall expire  
13                   on September 30, 2023.”;

14           (2) in paragraph (2), by striking “paragraph  
15           (1) for a fiscal year” and inserting “paragraph  
16           (1)(A) for a fiscal year and not reserved for the pur-  
17           pose described in paragraph (1)(B)(i)”;

18           (3) in paragraph (3)(A), by striking “paragraph  
19           (1) and not reserved under paragraph (2)” and in-  
20           serting “paragraph (1)(A) and not reserved under  
21           paragraph (1)(B)(i) or (2)”.



1 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**  
2 **PAREDNESS AND RESPONSE SYSTEMS.**

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

6 **“SEC. 319C-3. GUIDELINES FOR REGIONAL HEALTH CARE**  
7 **EMERGENCY PREPAREDNESS AND RESPONSE**  
8 **SYSTEMS.**

9 “(a) PURPOSE.—It is the purpose of this section to  
10 identify and provide guidelines for regional systems of hos-  
11 pitals, health care facilities, and other public and private  
12 sector entities, with varying levels of capability to treat  
13 patients and increase medical surge capacity during, in ad-  
14 vance of, and immediately following a public health emer-  
15 gency, including threats posed by one or more chemical,  
16 biological, radiological, and nuclear agents, including  
17 emerging infectious diseases.

18 “(b) GUIDELINES.—The Assistant Secretary for Pre-  
19 paredness and Response, in consultation with the Director  
20 of the Centers for Disease Control and Prevention, the Ad-  
21 ministrator of the Centers for Medicare & Medicaid Serv-  
22 ices, the Administrator of the Health Resources and Serv-  
23 ices Administration, the Commissioner of Food and  
24 Drugs, the Assistant Secretary for Mental Health and  
25 Substance Use, the Assistant Secretary of Labor for Occu-  
26 pational Safety and Health, the Secretary of Veterans Af-

1   fairs, the heads of such other Federal agencies as the Sec-  
2   retary determines to be appropriate, and State, local, trib-  
3   al, and territorial public health officials, shall, not later  
4   than 2 years after the date of enactment of this section—

5           “(1) identify and develop a set of guidelines re-  
6   lating to practices and protocols for all-hazards pub-  
7   lic health emergency preparedness and response for  
8   hospitals and health care facilities to provide appro-  
9   priate patient care during, in advance of, or imme-  
10   diately following, a public health emergency, result-  
11   ing from one or more chemical, biological, radio-  
12   logical, or nuclear agents, including emerging infec-  
13   tious diseases (which may include existing practices,  
14   such as trauma care and medical surge capacity and  
15   capabilities), with respect to—

16           “(A) a regional approach to identifying  
17   hospitals and health care facilities based on  
18   varying capabilities and capacity to treat pa-  
19   tients affected by such emergency, including—

20           “(i) the manner in which the system  
21   will coordinate with and integrate the part-  
22   nerships and health care coalitions estab-  
23   lished under section 319C-2(b); and

24           “(ii) informing and educating appro-  
25   priate first responders and health care sup-

1           ply chain partners of the regional emer-  
2           gency preparedness and response capabili-  
3           ties and medical surge capacity of such  
4           hospitals and health care facilities in the  
5           community;

6           “(B) physical and technological infrastruc-  
7           ture, laboratory capacity, staffing, blood supply,  
8           and other supply chain needs, taking into ac-  
9           count resiliency, geographic considerations, and  
10          rural considerations;

11          “(C) protocols or best practices for the  
12          safety and personal protection of workers who  
13          handle human remains and health care workers  
14          (including with respect to protective equipment  
15          and supplies, waste management processes, and  
16          decontamination), sharing of specialized experi-  
17          ence among the health care workforce, behav-  
18          ioral health, psychological resilience, and train-  
19          ing of the workforce, as applicable;

20          “(D) in a manner that allows for disease  
21          containment (within the meaning of section  
22          2802(b)(2)(B)), coordinated medical triage,  
23          treatment, and transportation of patients, based  
24          on patient medical need (including patients in  
25          rural areas), to the appropriate hospitals or

1 health care facilities within the regional system  
2 or, as applicable and appropriate, between sys-  
3 tems in different States or regions; and

4 “(E) the needs of children and other at-  
5 risk individuals;

6 “(2) make such guidelines available on the  
7 internet website of the Department of Health and  
8 Human Services in a manner that does not com-  
9 promise national security; and

10 “(3) update such guidelines as appropriate, in-  
11 cluding based on input received pursuant to sub-  
12 sections (c), (e), and (f), to address new and emerg-  
13 ing public health threats.

14 “(c) CONSIDERATIONS.—In identifying, developing,  
15 and updating guidelines under subsection (b), the Assist-  
16 ant Secretary for Preparedness and Response shall—

17 “(1) include input from hospitals and health  
18 care facilities, including health care coalitions under  
19 section 319C–2, State, local, tribal, and territorial  
20 public health departments, and health care or sub-  
21 ject matter experts, including experts with relevant  
22 expertise in chemical, biological, radiological, or nu-  
23 clear threats, and emerging infectious disease as the  
24 Assistant Secretary determines appropriate, to meet  
25 the goals under section 2802(b)(3);

1           “(2) consult and engage with appropriate  
2 health care providers and professionals, including  
3 physicians, nurses, first responders, health care fa-  
4 cilities (including hospitals, primary care clinics,  
5 community health centers, mental health facilities,  
6 ambulatory care facilities, and dental health facili-  
7 ties), pharmacies, emergency medical providers,  
8 trauma care providers, environmental health agen-  
9 cies, public health laboratories, poison control cen-  
10 ters, blood banks, and other experts that the Assist-  
11 ant Secretary determines appropriate, to meet the  
12 goals under section 2802(b)(3);

13           “(3) consider feedback related to financial im-  
14 plications for hospitals, health care facilities, public  
15 health agencies, laboratories, and other entities en-  
16 gaged in regional preparedness planning to imple-  
17 ment and follow such guidelines, as applicable; and

18           “(4) consider financial requirements and poten-  
19 tial incentives for entities to prepare for, and re-  
20 spond to, public health emergencies as part of the  
21 regional health care emergency preparedness and re-  
22 sponse system.

23           “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-  
24 retary for Preparedness and Response, in consultation  
25 with the Director of the Centers for Disease Control and



1 Prevention and the Assistant Secretary of Labor for Occu-  
2 pational Safety and Health, may provide technical assist-  
3 ance and consultation towards meeting the guidelines de-  
4 scribed in subsection (b).

5 “(e) DEMONSTRATION PROJECT FOR REGIONAL  
6 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-  
7 TEMS.—

8 “(1) IN GENERAL.—The Assistant Secretary for  
9 Preparedness and Response may establish a dem-  
10 onstration project pursuant to the development and  
11 implementation of guidelines under subsection (b) to  
12 award grants to improve medical surge capacity for  
13 all hazards, build and integrate regional medical re-  
14 sponse capabilities, improve specialty care expertise  
15 for all-hazards response, and coordinate medical pre-  
16 paredness and response across State, local, tribal,  
17 territorial, and regional jurisdictions.

18 “(2) SUNSET.—The authority under this sub-  
19 section shall expire on September 30, 2023.

20 “(f) GAO REPORT TO CONGRESS.—

21 “(1) REPORT.—Not later than 3 years after the  
22 date of enactment of this section, the Comptroller  
23 General of the United States (referred to in this  
24 subsection as the ‘Comptroller General’) shall submit  
25 to the Committee on Health, Education, Labor, and

1 Pensions and the Committee on Finance of the Sen-  
2 ate and the Committee on Energy and Commerce  
3 and the Committee on Ways and Means of the  
4 House of Representatives, a report on the extent to  
5 which hospitals and health care facilities have imple-  
6 mented the recommended guidelines under sub-  
7 section (b), including an analysis and evaluation of  
8 any challenges hospitals or health care facilities ex-  
9 perience in implementing such guidelines.

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

12 “(A) data on the preparedness and re-  
13 sponse capabilities that have been informed by  
14 the guidelines under subsection (b) to improve  
15 regional emergency health care preparedness  
16 and response capability, including hospital and  
17 health care facility capacity and medical surge  
18 capabilities to prepare for, and respond to, pub-  
19 lic health emergencies; and

20 “(B) recommendations to reduce gaps in  
21 incentives for regional health partners, includ-  
22 ing hospitals and health care facilities to im-  
23 prove capacity and medical surge capabilities to  
24 prepare for, and respond to, public health emer-  
25 gencies, consistent with subsection (a), which

1           may include consideration of facilities partici-  
2           pating in programs under section 319C-2, pro-  
3           grams under the Centers for Medicare & Med-  
4           icaid Services (including innovative health care  
5           delivery and payment models), and input from  
6           private sector financial institutions.

7           “(3) CONSULTATION.—In carrying out para-  
8           graphs (1) and (2), the Comptroller General shall  
9           consult with the heads of appropriate Federal agen-  
10          cies, including—

11                 “(A) the Assistant Secretary for Prepared-  
12                 ness and Response;

13                 “(B) the Director of the Centers for Dis-  
14                 ease Control and Prevention;

15                 “(C) the Administrator of the Centers for  
16                 Medicare & Medicaid Services;

17                 “(D) the Assistant Secretary for Mental  
18                 Health and Substance Use;

19                 “(E) the Assistant Secretary of Labor for  
20                 Occupational Safety and Health;

21                 “(F) the Secretary of Veterans Affairs;  
22                 and

23                 “(G) the heads of such other Federal agen-  
24                 cies as the Secretary determines appropriate.”.



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

6 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-  
7 PORATION OF REGIONALIZED EMERGENCY PREPARED-  
8 NESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C.  
9 300hh–1(b)(3)) is amended—

10 (1) in the matter preceding subparagraph (A),  
11 by striking “including mental health” and inserting  
12 “including pharmacies, mental health facilities,”;  
13 and

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

16 “(G) Optimizing a coordinated and flexible  
17 approach to the emergency response and med-  
18 ical surge capacity of hospitals, other health  
19 care facilities, critical care, trauma care (which  
20 may include trauma centers), and emergency  
21 medical systems, which may include the imple-  
22 mentation of guidelines for regional health care  
23 emergency preparedness and response systems  
24 under section 319C–3.”.

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

3 (1) STATE AND LOCAL SECURITY.—Section  
4 319C–1(e) (42 U.S.C. 247d–3a(e)) is amended by  
5 striking “, and local emergency plans.” and inserting  
6 “, local emergency plans, and any regional health  
7 care emergency preparedness and response system  
8 established pursuant to the applicable guidelines  
9 under section 319C–3.”.

10 (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)  
11 (42 U.S.C. 247d-3b(d)(1)(A)) is amended—

12 (A) in clause (i), by striking “; and” and  
13 inserting “;”

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

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

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

20 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
21 **TRAUMA READINESS.**

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

1 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**  
2 **FOR TRAUMA READINESS GRANT PROGRAM**

3 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**  
4 **TRAUMA READINESS GRANT PROGRAM.**

5 **“(a) MILITARY TRAUMA TEAM PLACEMENT PRO-**  
6 **GRAM.—**

7 **“(1) IN GENERAL.—**The Secretary, acting  
8 through the Assistant Secretary for Preparedness  
9 and Response and in consultation with the Secretary  
10 of Defense, shall award grants to not more than 20  
11 eligible high acuity trauma centers to enable military  
12 trauma teams to provide, on a full-time basis, trauma  
13 care and related acute care at such trauma cen-  
14 ters.

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

18 **“(A) shall be for a period of not fewer**  
19 **than 3 fiscal years and not more than 5 fiscal**  
20 **years (and may be renewed at the end of such**  
21 **period); and**

22 **“(B) shall be in an amount that does not**  
23 **exceed \$1,000,000 per fiscal year.**

24 **“(b) MILITARY TRAUMA CARE PROVIDER PLACE-**  
25 **MENT PROGRAM.—**

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

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

11           “(A) shall be for a period of at least 1 fis-  
12 cal year and not more than 3 fiscal years (and  
13 may be renewed at the end of such period); and

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

16           “(i) \$100,000 for each military trau-  
17 ma care provider that is a physician at  
18 such eligible trauma center; and

19           “(ii) \$50,000 for each other military  
20 trauma care provider at such eligible trau-  
21 ma center.

22           “(c) GRANT REQUIREMENTS.—

23           “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-  
24 GENCIES.—As a condition of receipt of a grant  
25 under this section, a grant recipient shall agree to

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

3 “(A) be deployed by the Secretary of De-  
4 fense for military operations, for training, or  
5 for response to a mass casualty incident; and

6 “(B) be deployed by the Secretary of  
7 Health and Human Services for response to a  
8 public health emergency pursuant to section  
9 319.

10 “(2) USE OF FUNDS.—Grants awarded under  
11 this section to an eligible trauma center may be used  
12 to train and incorporate military trauma care pro-  
13 viders into such trauma center, including incorpora-  
14 tion into operational exercises and training drills re-  
15 lated to public health emergencies, expenditures for  
16 malpractice insurance, office space, information  
17 technology, specialty education and supervision,  
18 trauma programs, and State license fees for such  
19 military trauma care providers.

20 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
21 tion shall be construed to affect any other provision of law  
22 that preempts State licensing requirements for health care  
23 professionals with respect to military trauma care pro-  
24 viders.

25 “(e) REPORTING REQUIREMENTS.—

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

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

12                  “(B) the ability to maintain the integration  
13                  of the military trauma providers or teams of  
14                  providers as part of the trauma center, includ-  
15                  ing the financial effect of such grant on the  
16                  trauma center;

17                  “(C) the educational effect on resident  
18                  trainees in centers where military trauma teams  
19                  are assigned;

20                  “(D) any research conducted during such  
21                  fiscal year supported by such grant; and

22                  “(E) any other information required by the  
23                  Secretaries for the purpose of evaluating the ef-  
24                  fect of such grant.

1           “(2) REPORT TO CONGRESS.—Not less than  
2           once every 2 fiscal years, the Secretary, in consulta-  
3           tion with the Secretary of Defense, shall submit a  
4           report to the congressional committees of jurisdic-  
5           tion that includes information on the effect of plac-  
6           ing military trauma care providers in trauma centers  
7           awarded grants under this section on—

8                   “(A) maintaining military trauma care  
9                   providers’ readiness and ability to respond to  
10                  and treat battlefield injuries;

11                  “(B) providing health care to civilian trau-  
12                  ma patients in urban and rural settings;

13                  “(C) the capability of trauma centers and  
14                  military trauma care providers to increase med-  
15                  ical surge capacity, including as a result of a  
16                  large scale event;

17                  “(D) the ability of grant recipients to  
18                  maintain the integration of the military trauma  
19                  providers or teams of providers as part of the  
20                  trauma center;

21                  “(E) efforts to incorporate military trauma  
22                  care providers into operational exercises and  
23                  training and drills for public health emer-  
24                  gencies; and

1           “(F) the capability of military trauma care  
2           providers to participate as part of a medical re-  
3           sponse during or in advance of a declared pub-  
4           lic health emergency.

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

6           “(1) ELIGIBLE TRAUMA CENTER.—The term  
7           ‘eligible trauma center’ means a Level I, II, or III  
8           trauma center that satisfies each of the following:

9           “(A) Such trauma center has an agree-  
10          ment with the Secretary of Defense to enable  
11          military trauma care providers to provide trau-  
12          ma care and related acute care at such trauma  
13          center.

14          “(B) Such trauma center utilizes a risk-ad-  
15          justed benchmarking system and metrics to  
16          measure performance, quality, and patient out-  
17          comes.

18          “(C) Such trauma center demonstrates a  
19          need for integrated military trauma care pro-  
20          viders to maintain or improve the trauma clin-  
21          ical capability of such trauma center.

22          “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-  
23          TER.—The term ‘eligible high acuity trauma center’  
24          means a Level I trauma center that satisfies each of  
25          the following:



1           “(A) Such trauma center has an agree-  
2           ment with the Secretary of Defense to enable  
3           military trauma teams to provide trauma care  
4           and related acute care at such trauma center.

5           “(B) At least 20 percent of patients treat-  
6           ed at such trauma center in the most recent 3-  
7           month period for which data is available are  
8           treated for a major trauma at such trauma cen-  
9           ter.

10           “(C) Such trauma center utilizes a risk-ad-  
11           justed benchmarking system and metrics to  
12           measure performance, quality, and patient out-  
13           comes.

14           “(D) Such trauma center is an academic  
15           training center—

16                   “(i) affiliated with a medical school;

17                   “(ii) that maintains residency pro-  
18                   grams and fellowships in critical trauma  
19                   specialties and subspecialties, and provides  
20                   education and supervision of military trau-  
21                   ma team members according to those spe-  
22                   cialties and subspecialties; and

23                   “(iii) that undertakes research in the  
24                   prevention and treatment of traumatic in-  
25                   jury.

1           “(E) Such trauma center serves as a med-  
2           ical and public health preparedness and re-  
3           sponse leader for its community, such as by  
4           participating in a partnership for State and re-  
5           gional hospital preparedness established under  
6           section 319C-2 or 319C-3.

7           “(3) MAJOR TRAUMA.—The term ‘major trau-  
8           ma’ means an injury that is greater than or equal  
9           to 15 on the injury severity score.

10           “(4) MILITARY TRAUMA TEAM.—The term  
11           ‘military trauma team’ means a complete military  
12           trauma team consisting of military trauma care pro-  
13           viders specializing in providing trauma care.

14           “(5) MILITARY TRAUMA CARE PROVIDER.—The  
15           term ‘military trauma care provider’ means a mem-  
16           ber of the Armed Forces who furnishes emergency,  
17           critical care, and other trauma acute care services,  
18           including a physician, surgeon or military surgeon,  
19           physician assistant, nurse, nurse practitioner, res-  
20           piratory therapist, flight paramedic, combat medic,  
21           or enlisted medical technician, or other military  
22           trauma care provider as the Secretary determines  
23           appropriate.

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

1 priated \$6,800,000 for each of fiscal years 2019 through  
2 2023.”.

3 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**  
4 **UATIONAL AWARENESS AND BIOSURVEIL-**  
5 **LANCE CAPABILITIES.**

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

9 (1) in the section heading, by striking “**REVI-**  
10 **TALIZING**” and inserting “**FACILITIES AND CA-**  
11 **PACITIES OF**”;

12 (2) in subsection (a)—

13 (A) in the subsection heading, by striking  
14 “**FACILITIES; CAPACITIES**” and inserting “**IN**  
15 **GENERAL**”;

16 (B) in paragraph (1), by striking “and im-

17 proved” and inserting “, improved, and appro-

18 priately maintained”;

19 (C) in paragraph (3), in the matter pre-

20 ceding subparagraph (A), by striking “expand,

21 enhance, and improve” and inserting “expand,

22 improve, enhance, and appropriately maintain”;

23 and

24 (D) by adding at the end the following:

1           “(4) STUDY OF RESOURCES FOR FACILITIES  
2           AND CAPACITIES.—Not later than June 1, 2022, the  
3           Comptroller General of the United States shall con-  
4           duct a study on Federal spending in fiscal years  
5           2013 through 2018 for activities authorized under  
6           this subsection. Such study shall include a review  
7           and assessment of obligations and expenditures di-  
8           rectly related to each activity under paragraphs (2)  
9           and (3), including a specific accounting of, and de-  
10          lineation between, obligations and expenditures in-  
11          curred for the construction, renovation, equipping,  
12          and security upgrades of facilities and associated  
13          contracts under this subsection, and the obligations  
14          and expenditures incurred to establish and improve  
15          the situational awareness and biosurveillance net-  
16          work under subsection (b), and shall identify the  
17          agency or agencies incurring such obligations and  
18          expenditures.”;

19           (3) in subsection (b)—

20           (A) in the subsection heading, by striking  
21           “NATIONAL” and inserting “ESTABLISHMENT  
22           OF SYSTEMS OF PUBLIC HEALTH ”;

23           (B) in paragraph (1)(B), by inserting “im-  
24           munization information systems,” after “cen-  
25           ters,”; and

1 (C) in paragraph (2)—

2 (i) by inserting “develop a plan to,  
3 and” after “The Secretary shall”; and

4 (ii) by inserting “and in a form read-  
5 ily usable for analytical approaches” after  
6 “in a secure manner”; and

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

9 “(3) STANDARDS.—

10 “(A) IN GENERAL.—Not later than 1 year  
11 after the date of the enactment of the Pan-  
12 demic and All-Hazards Preparedness and Ad-  
13 vancing Innovation Act of 2018, the Secretary,  
14 in cooperation with health care providers, State,  
15 local, tribal, and territorial public health offi-  
16 cials, and relevant Federal agencies (including  
17 the Office of the National Coordinator for  
18 Health Information Technology and the Na-  
19 tional Institute of Standards and Technology),  
20 shall, as necessary, adopt technical and report-  
21 ing standards, including standards for inter-  
22 operability as defined by section 3000, for net-  
23 works under paragraph (1) and update such  
24 standards as necessary. Such standards shall be  
25 made available on the internet website of the

1 Department of Health and Human Services, in  
2 a manner that does not compromise national se-  
3 curity.

4 “(B) DEFERENCE TO STANDARDS DEVEL-  
5 OPMENT ORGANIZATIONS.—In adopting and im-  
6 plementing standards under this subsection and  
7 subsection (c), the Secretary shall give def-  
8 erence to standards published by standards de-  
9 velopment organizations and voluntary con-  
10 sensus-based standards entities.”;

11 (4) in subsection (c)—

12 (A) in paragraph (1)—

13 (i) by striking “Not later than 2 years  
14 after the date of enactment of the Pan-  
15 demic and All-Hazards Preparedness Re-  
16 authorization Act of 2013, the Secretary”  
17 and inserting “The Secretary”;

18 (ii) by inserting “, and improve as ap-  
19 plicable and appropriate,” after “shall es-  
20 tablish”;

21 (iii) by striking “of rapid” and insert-  
22 ing “of, rapid”; and

23 (iv) by striking “such connectivity”  
24 and inserting “such interoperability”;

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

3 “(2) COORDINATION AND CONSULTATION.—In  
4 establishing and improving the network under para-  
5 graph (1) the Secretary shall—

6 “(A) facilitate coordination among agencies  
7 within the Department of Health and Human  
8 Services that provide or have the potential to  
9 provide information and data to, and analyses  
10 for, the situational awareness and biosurveil-  
11 lance network under paragraph (1), including  
12 coordination among relevant agencies related to  
13 health care services, the facilitation of health  
14 information exchange (including the Office of  
15 the National Coordinator for Health Informa-  
16 tion Technology), and public health emergency  
17 preparedness and response; and

18 “(B) consult with the Secretary of Agri-  
19 culture, the Secretary of Commerce (and the  
20 Director of the National Institute of Standards  
21 and Technology), the Secretary of Defense, the  
22 Secretary of Homeland Security, and the Sec-  
23 retary of Veterans Affairs, and the heads of  
24 other Federal agencies, as the Secretary deter-  
25 mines appropriate.”;

1 (C) in paragraph (3)—

2 (i) by redesignating subparagraphs  
3 (A) through (E) as clauses (i) through (v),  
4 respectively, and adjusting the margins ac-  
5 cordingly;

6 (ii) in clause (iv), as so redesign-  
7 nated—

8 (I) by inserting “immunization  
9 information systems,” after “poison  
10 control,”; and

11 (II) by striking “ and clinical  
12 laboratories” and inserting “, clinical  
13 laboratories, and public environmental  
14 health agencies”;

15 (iii) by striking “The network” and  
16 inserting the following:

17 “(A) IN GENERAL.—The network”; and

18 (iv) by adding at the end the fol-  
19 lowing:

20 “(B) REVIEW.—Not later than 2 years  
21 after the date of the enactment of the Pan-  
22 demic and All-Hazards Preparedness and Ad-  
23 vancing Innovation Act of 2018 and every 6  
24 years thereafter, the Secretary shall conduct a  
25 review of the elements described in subpara-



1 graph (A). Such review shall include a discus-  
2 sion of the addition of any elements pursuant to  
3 clause (v), including elements added to advanc-  
4 ing new technologies, and identify any chal-  
5 lenges in the incorporation of elements under  
6 subparagraph (A). The Secretary shall provide  
7 such review to the congressional committees of  
8 jurisdiction.”;

9 (D) in paragraph (5)—

10 (i) by redesignating subparagraphs  
11 (A) through (D) as clauses (i) through  
12 (iv), respectively, and adjusting the mar-  
13 gins accordingly;

14 (ii) by striking “In establishing” and  
15 inserting the following:

16 “(A) IN GENERAL.—In establishing”;

17 (iii) by adding at the end the fol-  
18 lowing:

19 “(B) PUBLIC MEETING.—

20 “(i) IN GENERAL.—Not later than  
21 180 days after the date of enactment of  
22 the Pandemic and All-Hazards Prepared-  
23 ness and Advancing Innovation Act of  
24 2018, the Secretary shall convene a public  
25 meeting for purposes of discussing and

1 providing input on the potential goals,  
2 functions, and uses of the network de-  
3 scribed in paragraph (1) and incorporating  
4 the elements described in paragraph  
5 (3)(A).

6 “(ii) EXPERTS.—The public meeting  
7 shall include representatives of relevant  
8 Federal agencies (including representatives  
9 from the Office of the National Coordi-  
10 nator for Health Information Technology  
11 and the National Institute of Standards  
12 and Technology), State, local, tribal, and  
13 territorial public health officials, stake-  
14 holders with expertise in biosurveillance  
15 and situational awareness, and stake-  
16 holders with expertise in capabilities rel-  
17 evant to biosurveillance and situational  
18 awareness, such as experts in informatics  
19 and data analytics (including experts in  
20 prediction, modeling, or forecasting), and  
21 other representatives as the Secretary de-  
22 termines appropriate.

23 “(iii) TOPICS.—Such public meeting  
24 shall include a discussion of—

- 1                   “(I) data elements, including  
2                   minimal or essential data elements,  
3                   that are voluntarily provided for such  
4                   network, which may include elements  
5                   from public health and public and pri-  
6                   vate health care entities, to the extent  
7                   practicable;
- 8                   “(II) standards and implementa-  
9                   tion specifications that may improve  
10                  the collection, analysis, and interpre-  
11                  tation of data during a public health  
12                  emergency;
- 13                  “(III) strategies to encourage the  
14                  access, exchange, and use of informa-  
15                  tion;
- 16                  “(IV) considerations for State,  
17                  local, tribal, and territorial capabilities  
18                  and infrastructure related to data ex-  
19                  change and interoperability;
- 20                  “(V) privacy and security protec-  
21                  tions provided at the Federal, State,  
22                  local, tribal, and territorial levels, and  
23                  by nongovernmental stakeholders; and

1 “(VI) opportunities for the incor-  
2 poration of innovative technologies to  
3 improve the network.”; and

4 (iv) in subparagraph (A), as so des-  
5 ignated by clause (ii)—

6 (I) in clause (i), as so redesign-  
7 nated—

8 (aa) by striking “as deter-  
9 mined” and inserting “as adopt-  
10 ed”; and

11 (bb) by inserting “and the  
12 National Institute of Standards  
13 and Technology” after “Office of  
14 the National Coordinator for  
15 Health Information Technology”;

16 (II) in clause (iii), as so redesign-  
17 nated, by striking “; and” and insert-  
18 ing a semicolon;

19 (III) in clause (iv), as so redesign-  
20 nated, by striking the period and in-  
21 serting “; and”; and

22 (IV) by adding at the end the fol-  
23 lowing:

24 “(v) pilot test standards and imple-  
25 mentation specifications, consistent with

1           the process described in section  
2           3002(b)(3)(C), which State, local, tribal,  
3           and territorial public health entities may  
4           utilize, on a voluntary basis, as a part of  
5           the network.”;

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

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

10          “(6) STRATEGY AND IMPLEMENTATION  
11          PLAN.—

12                 “(A) IN GENERAL.—Not later than 18  
13                 months after the date of enactment of the Pan-  
14                 demic and All-Hazards Preparedness and Ad-  
15                 vancing Innovation Act of 2018, the Secretary  
16                 shall submit to the congressional committees of  
17                 jurisdiction a coordinated strategy and an ac-  
18                 companying implementation plan that—

19                         “(i) is informed by the public meeting  
20                         under paragraph (5)(B);

21                         “(ii) includes a review and assessment  
22                         of existing capabilities of the network and  
23                         related infrastructure, including input pro-  
24                         vided by the public meeting under para-  
25                         graph (5)(B);

1                   “(iii) identifies and demonstrates the  
2                   measurable steps the Secretary will carry  
3                   out to—

4                   “(I) develop, implement, and  
5                   evaluate the network described in  
6                   paragraph (1), utilizing elements de-  
7                   scribed in paragraph (3)(A);

8                   “(II) modernize and enhance bio-  
9                   surveillance activities, including strat-  
10                  egies to include innovative tech-  
11                  nologies and analytical approaches  
12                  (including prediction and forecasting  
13                  for pandemics and all-hazards) from  
14                  public and private entities;

15                  “(III) improve information shar-  
16                  ing, coordination, and communication  
17                  among disparate biosurveillance sys-  
18                  tems supported by the Department of  
19                  Health and Human Services, includ-  
20                  ing the identification of methods to  
21                  improve accountability, better utilize  
22                  resources and workforce capabilities,  
23                  and incorporate innovative tech-  
24                  nologies within and across agencies;  
25                  and

1                   “(IV) test and evaluate capabili-  
2                   ties of the interoperable network of  
3                   systems to improve situational aware-  
4                   ness and biosurveillance capabilities;

5                   “(iv) includes performance measures  
6                   and the metrics by which performance  
7                   measures will be assessed with respect to  
8                   the measurable steps under clause (iii);  
9                   and

10                   “(v) establishes dates by which each  
11                   measurable step under clause (iii) will be  
12                   implemented.”.

13                   “(B) ANNUAL BUDGET PLAN.—Not later  
14                   than 2 years after the date of enactment of the  
15                   Pandemic and All-Hazards Preparedness and  
16                   Advancing Innovation Act of 2018 and on an  
17                   annual basis thereafter, in accordance with the  
18                   strategy and implementation plan under this  
19                   paragraph, the Secretary shall, taking into ac-  
20                   count recommendations provided by the Na-  
21                   tional Biodefense Science Board, develop a  
22                   budget plan based on the strategy and imple-  
23                   mentation plan under this section. Such budget  
24                   plan shall include—

1           “(i) a summary of resources pre-  
2           viously expended to establish, improve, and  
3           utilize the nationwide public health situa-  
4           tional awareness and biosurveillance net-  
5           work under paragraph (1);

6           “(ii) estimates of costs and resources  
7           needed to establish and improve the net-  
8           work under paragraph (1) according to the  
9           strategy and implementation plan under  
10          subparagraph (A);

11          “(iii) the identification of gaps and in-  
12          efficiencies in nationwide public health sit-  
13          uational awareness and biosurveillance ca-  
14          pabilities, resources, and authorities need-  
15          ed to address such gaps; and

16          “(iv) a strategy to minimize and ad-  
17          dress such gaps and improve inefficien-  
18          cies.”;

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

20                 (i) in subparagraph (A), by inserting  
21                 “(taking into account zoonotic disease, in-  
22                 cluding gaps in scientific understanding of  
23                 the interactions between human, animal,  
24                 and environmental health)” after “human  
25                 health”;



1 (ii) in subparagraph (B)—

2 (I) by inserting “and gaps in sur-  
3 veillance programs” after “surveil-  
4 lance programs”; and

5 (II) by striking “; and” and in-  
6 serting a semicolon;

7 (iii) in subparagraph (C)—

8 (I) by inserting “, animal health  
9 organizations related to zoonotic dis-  
10 ease,” after “health care entities”;  
11 and

12 (II) by striking the period and  
13 inserting “; and”; and

14 (iv) by adding at the end the fol-  
15 lowing:

16 “(D) provide recommendations to the Sec-  
17 retary on policies and procedures to complete  
18 the steps described in this paragraph in a man-  
19 ner that is consistent with section 2802.”; and

20 (H) by adding at the end the following:

21 “(8) SITUATIONAL AWARENESS AND BIO-  
22 SURVEILLANCE AS A NATIONAL SECURITY PRI-  
23 ORITY.—The Secretary, on a periodic basis as appli-  
24 cable and appropriate, shall meet with the Director  
25 of National Intelligence to inform the development

1 and capabilities of the nationwide public health situ-  
2 ational awareness and biosurveillance network.”;

3 (5) in subsection (d)—

4 (A) in paragraph (1)—

5 (i) by inserting “environmental health  
6 agencies,” after “public health agencies,”;

7 and

8 (ii) by inserting “immunization pro-  
9 grams,” after “poison control centers,”;

10 and

11 (B) in paragraph (2)—

12 (i) in subparagraph (B), by striking  
13 “and” at the end;

14 (ii) in subparagraph (C), by striking  
15 the period and inserting “; and”; and

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

18 “(D) an implementation plan that may in-  
19 clude measurable steps to achieve the purposes  
20 described in paragraph (1).”; and

21 (C) by striking paragraph (5) and insert-  
22 ing the following:

23 “(5) TECHNICAL ASSISTANCE.—The Secretary  
24 may provide technical assistance to States, localities,  
25 tribes, and territories or a consortium of States, lo-

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

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

6 (7) by inserting after subsection (e) the fol-  
7 lowing:

8 “(f) PERSONNEL AUTHORITIES.—

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

13 “(A) appoint highly qualified individuals to  
14 scientific or professional positions at the Cen-  
15 ters for Disease Control and Prevention, not to  
16 exceed 30 such employees at any time (specific  
17 to positions authorized by this subsection), with  
18 expertise in capabilities relevant to biosurveil-  
19 lance and situational awareness, such as experts  
20 in informatics and data analytics (including ex-  
21 perts in prediction, modelling, or forecasting),  
22 and other related scientific or technical fields;  
23 and

24 “(B) compensate individuals appointed  
25 under subparagraph (A) in the same manner

1           and subject to the same terms and conditions in  
2           which individuals appointed under 9903 of title  
3           5, United States Code, are compensated, with-  
4           out regard to the provisions of chapter 51 and  
5           subchapter III of chapter 53 of that title relat-  
6           ing to classification and General Schedule pay  
7           rates.

8           “(2) LIMITATIONS.—The Secretary shall exer-  
9           cise the authority under paragraph (1) in a manner  
10          that is consistent with the limitations described in  
11          section 319F–1(e)(2).

12          “(g) TIMELINE.—The Secretary shall accomplish the  
13          purposes under subsections (b) and (c) no later than Sep-  
14          tember 30, 2023, and shall provide a justification to the  
15          congressional committees of jurisdiction for any missed or  
16          delayed implementation of measurable steps identified  
17          under subsection (c)(6)(A)(iii).

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

1 applicable and appropriate, on necessary improvements to  
2 the biosurveillance and situational awareness network.”.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-  
4 section (i) of section 319D (42 U.S.C. 247d-4), as redес-  
5 igned by subsection (a)(6), is amended by striking  
6 “\$138,300,000 for each of fiscal years 2014 through  
7 2018” and inserting “\$161,800,000 for each of fiscal  
8 years 2019 through 2023”.

9 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**  
10 **HEALTH EMERGENCY RAPID RESPONSE**  
11 **FUND.**

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

13 (1) in subsection (b)—

14 (A) in paragraph (1)—

15 (i) in the first sentence, by inserting

16 “or if the Secretary determines there is the  
17 significant potential for a public health  
18 emergency, to allow the Secretary to rap-  
19 idly respond to the immediate needs result-  
20 ing from such public health emergency or  
21 potential public health emergency” before  
22 the period; and

23 (ii) by inserting “The Secretary shall  
24 plan for the expedited distribution of funds

1 to appropriate agencies and entities.” after  
2 the first sentence;

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

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

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

9 “(A) facilitate coordination between and  
10 among Federal, State, local, tribal, and terri-  
11 torial entities and public and private health  
12 care entities that the Secretary determines may  
13 be affected by a public health emergency or po-  
14 tential public health emergency (including com-  
15 munication of such entities with relevant inter-  
16 national entities, as applicable);

17 “(B) make grants, provide for awards,  
18 enter into contracts, and conduct supportive in-  
19 vestigations pertaining to a public health emer-  
20 gency or potential public health emergency, in-  
21 cluding further supporting programs under sec-  
22 tion 319C–1, 319C–2, or 319C–3;

23 “(C) facilitate and accelerate, as applica-  
24 ble, advanced research and development of secu-  
25 rity countermeasures (as defined in section

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

7           “(D) strengthen biosurveillance capabilities  
8           and laboratory capacity to identify, collect, and  
9           analyze information regarding such public  
10          health emergency or potential public health  
11          emergency, including the systems under section  
12          319D;

13          “(E) support initial emergency operations  
14          and assets related to preparation and deploy-  
15          ment of intermittent disaster response per-  
16          sonnel expenses under section 2812, and the  
17          Medical Reserve Corps under section 2813; and

18          “(F) other activities, as the Secretary de-  
19          termines applicable and appropriate.”; and

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

22          “(4) REVIEW.—Not later than 2 years after the  
23          date of enactment of the Pandemic and All-Hazards  
24          Preparedness and Advancing Innovation Act of  
25          2018, the Secretary, in coordination with the Assist-

1 ant Secretary for Preparedness and Response, shall  
2 conduct a review of the Fund under this section, and  
3 provide recommendations to the Committee on  
4 Health, Education, Labor, and Pensions and the  
5 Committee on Appropriations of the Senate and the  
6 Committee on Energy and Commerce and the Com-  
7 mittee on Appropriations of the House of Represent-  
8 atives on policies to improve such Fund for the uses  
9 described in paragraph (2).

10 “(5) GAO REPORT.—Not later than 4 years  
11 after the date of enactment of the Pandemic and  
12 All-Hazards Preparedness and Advancing Innovation  
13 Act of 2018, the Comptroller General of the United  
14 States shall conduct a review of the Fund under this  
15 section, including the uses and the resources avail-  
16 able in the Fund.”; and

17 (2) in subsection (c)—

18 (A) by inserting “rapidly respond to public  
19 health emergencies or potential public health  
20 emergencies and” after “used to”; and

21 (B) by striking “section.” and inserting  
22 “Act or funds otherwise provided for emergency  
23 response.”.



1 **SEC. 207. IMPROVING PREPAREDNESS FOR AND RESPONSE**  
2 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**  
3 **GENCY VOLUNTEERS.**

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

5 (1) in subsection (a), by adding at the end the  
6 following: “Such health care professionals may in-  
7 clude members of the National Disaster Medical  
8 System, members of the Medical Reserve Corps, and  
9 individual health care professionals.”;

10 (2) in subsection (i) by adding at the end “In  
11 order to inform the development of such mechanisms  
12 by States, the Secretary shall make available infor-  
13 mation and material provided by States that have  
14 developed mechanisms to waive the application of li-  
15 censing requirements to applicable health profes-  
16 sionals seeking to provide medical services during a  
17 public health emergency. Such information shall be  
18 made publicly available in a manner that does not  
19 compromise national security.”; and

20 (3) in subsection (k) by striking “\$2014  
21 through 2018” and inserting “2019 through 2023”.

22 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**  
23 **TEER HEALTH CARE PROFESSIONALS.**

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

1 **“SEC. 319I-1. HEALTH CARE PROFESSIONALS ASSISTING**  
2 **DURING A PUBLIC HEALTH EMERGENCY.**

3 “(a) LIMITATION ON LIABILITY.—Notwithstanding  
4 any other provision of law, a health care professional who  
5 is a member of the Medical Reserve Corps under section  
6 2813 or who is included in the verification network under  
7 section 319I and who—

8 “(1) is responding to a public health emergency  
9 declared under section 319(a) during the initial 90-  
10 day period of the public health emergency deter-  
11 mination (excluding any period covered by a renewal  
12 of such determination);

13 “(2) is alleged to be liable for an act or omis-  
14 sion—

15 “(A) during the 90-day period of the pub-  
16 lic health emergency described in paragraph (1)  
17 and related to the treatment of individuals in  
18 need of health care services due to such public  
19 health emergency;

20 “(B) in the State or States in which the  
21 public health emergency is declared;

22 “(C) in the health care professional’s ca-  
23 pacity as a member of the Medical Reserve  
24 Corps or a professional included in the  
25 verification network under section 319I; and

1           “(D) in the course of providing services  
2           that are within the scope of the license, reg-  
3           istration, or certification of the professional, as  
4           defined by the State of licensure, registration,  
5           or certification; and

6           “(3) prior to the rendering of such act or omis-  
7           sion, was authorized by the State’s authorization of  
8           a deploying State’s Emergency System for Advance  
9           Registration of Volunteer Health Professionals de-  
10          scribed in section 319I or the Medical Reserve Corps  
11          established under section 2813, to provide health  
12          care services,  
13          shall be subject only to the State liability laws of the State  
14          in which such act or omission occurred, in the same man-  
15          ner and to the same extent as a similar health care profes-  
16          sional who is a resident of such State would be subject  
17          to such State laws, except with respect to the licensure,  
18          registration, and certification of such individual.

19          “(b) VOLUNTEER PROTECTION ACT.—Nothing in  
20          this section shall be construed to affect an individual’s  
21          right to protections under the Volunteer Protection Act  
22          of 1997.

23          “(c) PREEMPTION.—This section shall supercede the  
24          laws of any State that would subject a health care profes-  
25          sional described in subsection (a) to the liability laws of

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

3 “(d) DEFINITIONS.—In this section:

4 “(1) The term ‘health care professional’ means  
5 an individual licensed, registered, or certified under  
6 Federal or State laws or regulations to provide  
7 health care services.

8 “(2) The term ‘health care services’ means any  
9 services provided by a health care professional, or by  
10 any individual working under the supervision of a  
11 health care professional, that relate to—

12 “(A) the diagnosis, prevention, or treat-  
13 ment of any human disease or impairment; or

14 “(B) the assessment or care of the health  
15 of human beings.”.

16 (b) EFFECTIVE DATE.—

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

21 (2) APPLICATION.—Section 319I–1 of the Pub-  
22 lic Health Service Act, as added by subsection (a),  
23 applies to a claim for harm only if the act or omis-  
24 sion that caused such harm occurred on or after the  
25 effective date described in paragraph (1).

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

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

9 (2) the number of health care providers who are  
10 credentialed to provide services during the period of  
11 a public health emergency declaration, including  
12 those who are credentialed through programs estab-  
13 lished in the verification network pursuant to such  
14 section 319I and those credentialed by authorities  
15 within the State in which the emergency occurred;

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

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

1 vider organizations utilize such program for pur-  
2 poses of volunteering during public health emer-  
3 gencies.

## 4 **TITLE III—REACHING ALL** 5 **COMMUNITIES**

### 6 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-** 7 **GENCY RESPONSE WORKFORCE.**

8 (a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause  
9 (ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh–  
10 11(a)(3)(A)) is amended to read as follows:

11 “(ii) be present at locations, and for  
12 limited periods of time, specified by the  
13 Secretary on the basis that the Secretary  
14 has determined that a location is at risk of  
15 a public health emergency during the time  
16 specified, or there is a significant potential  
17 for a public health emergency.”.

18 (b) VOLUNTEER MEDICAL RESERVE CORPS.—Sec-  
19 tion 2813(a) (42 U.S.C. 42 U.S.C. 300hh–15(a)) is  
20 amended by striking the second sentence and inserting  
21 “The Secretary may appoint a Director to head the Corps  
22 and oversee the activities of the Corps chapters that exist  
23 at the State, local, and tribal levels.”

1           (c) REVIEW OF THE NATIONAL DISASTER MEDICAL  
2 SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh-  
3 11(b)(2)) is amended to read as follows:

4           “(2) JOINT REVIEW AND MEDICAL SURGE CA-  
5 PACITY STRATEGIC PLAN.—

6           “(A) REVIEW.—Not later than 180 days  
7 after the date of enactment of the Pandemic  
8 and All-Hazards Preparedness and Advancing  
9 Innovation Act of 2018, the Secretary, in co-  
10 ordination with the Secretary of Homeland Se-  
11 curity, the Secretary of Defense, and the Sec-  
12 retary of Veterans Affairs, shall conduct a joint  
13 review of the National Disaster Medical System.  
14 Such review shall include—

15           “(i) an evaluation of medical surge ca-  
16 pacity, as described in section 2803(a);

17           “(ii) an assessment of the available  
18 workforce of the intermittent disaster re-  
19 sponse personnel described in subsection  
20 (c);

21           “(iii) the capacity of the workforce de-  
22 scribed in clause (ii) to respond to all haz-  
23 ards, including capacity to simultaneously  
24 respond to multiple public health emer-

1 agencies and the capacity to respond to a  
2 nationwide public health emergency;

3 “(iv) the effectiveness of efforts to re-  
4 cruit, retain, and train such workforce; and

5 “(v) gaps that may exist in such  
6 workforce and recommendations for ad-  
7 dressing such gaps.

8 “(B) UPDATES.—As part of the National  
9 Health Security Strategy under section 2802,  
10 the Secretary shall update the findings from the  
11 review under subparagraph (A) and provide rec-  
12 ommendations to modify the policies of the Na-  
13 tional Disaster Medical System as necessary.”.

14 (d) NOTIFICATION OF NDMS SHORTAGE.—Section  
15 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding  
16 at the end the following:

17 “(3) SERVICE BENEFIT.—Individuals appointed  
18 to serve under this subsection shall be considered  
19 public safety officers under part L of title I of the  
20 Omnibus Crime Control and Safe Streets Act of  
21 1968. The Secretary shall provide notification to eli-  
22 gible individuals of any effect such designation may  
23 have on other benefits for which such individuals are  
24 eligible, including benefits from private entities.



1           “(4) NOTIFICATION.—Not later than 30 days  
2 after the date on which the Secretary determines the  
3 number of intermittent disaster response personnel  
4 of such System is insufficient to address a public  
5 health emergency or potential public health emer-  
6 gency, the Secretary shall submit to the congres-  
7 sional committees of jurisdiction a notification de-  
8 tailing the impact such shortage could have on meet-  
9 ing public health needs and emergency medical per-  
10 sonnel needs during a public health emergency, and  
11 any identified measures to address such shortage.

12           “(5) CERTAIN APPOINTMENTS.—

13           “(A) IN GENERAL.—If the Secretary deter-  
14 mines that the number of intermittent disaster  
15 response personnel within the National Disaster  
16 Medical System under this section is insuffi-  
17 cient to address a public health emergency or  
18 potential public health emergency, the Secretary  
19 may appoint candidates directly to personnel  
20 positions for intermittent disaster response  
21 within such system. The Secretary shall provide  
22 updates on the number of vacant or unfilled po-  
23 sitions within such system to the congressional  
24 committees of jurisdiction each quarter for  
25 which this authority is in effect.

1                   “(B) SUNSET.—The authority under this  
2                   paragraph shall expire on September 30,  
3                   2021.”.

4           (e) PUBLIC SAFETY OFFICER BENEFITS.—Section  
5 1204(9) of title I of the Omnibus Crime Control and Safe  
6 Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

7                   (1) in subparagraph (C)(ii), by striking “or” at  
8                   the end;

9                   (2) in subparagraph (D), by striking the period  
10                  and inserting “; or”; and

11                  (3) by inserting after subparagraph (D) the fol-  
12                  lowing:

13                         “(E) an individual appointed to the Na-  
14                         tional Disaster Medical System under section  
15                         2812 of the Public Health Service Act (42  
16                         U.S.C. 300hh–11) who is performing official  
17                         duties of the Department of Health and Human  
18                         Services, if those official duties are related to  
19                         responding to a public health emergency or po-  
20                         tential public health emergency, or other activi-  
21                         ties for which the Secretary of Health and  
22                         Human Services has activated such National  
23                         Disaster Medical System.”.

24           (f) NATIONAL DISASTER MEDICAL SYSTEM AUTHOR-  
25           IZATION OF APPROPRIATIONS.—Section 2812(g) (42

1 U.S.C. 300hh–11(g)) is amended by striking  
2 “\$52,700,000 for each of fiscal years 2014 through 2018”  
3 and inserting “\$57,400,000 for each of fiscal years 2019  
4 through 2023”.

5 (g) MEDICAL RESERVE CORPS. AUTHORIZATION OF  
6 APPROPRIATIONS.—Section 2813(i) (42 U.S.C. 300hh–  
7 15(i)) is amended by striking “2014 through 2018” and  
8 inserting “2019 through 2023”.

9 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**  
10 **PREPAREDNESS AND RESPONSE.**

11 (a) COORDINATION OF PREPAREDNESS.—Section  
12 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by  
13 adding at the end the following: “Such logistical support  
14 shall include working with other relevant Federal, State,  
15 local, tribal, and territorial public health officials and pri-  
16 vate sector entities to identify the critical infrastructure  
17 assets, systems, and networks needed for the proper func-  
18 tioning of the health care and public health sectors that  
19 need to be maintained through any emergency or disaster,  
20 including entities capable of assisting with, responding to,  
21 and mitigating the effect of a public health emergency,  
22 including an emergency under section 319, an emergency  
23 or major disaster under the Robert T. Stafford Disaster  
24 Relief and Emergency Assistance Act, or the National  
25 Emergencies Act, including by establishing methods to ex-

1 change critical information and deliver products consumed  
2 or used to preserve, protect, or sustain life, health, or safe-  
3 ty, and sharing of specialized expertise.”.

4 (b) MANUFACTURING CAPACITY.—Section  
5 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended  
6 by inserting “, and ancillary medical supplies to assist  
7 with the utilization of such products,” after “products”.

8 **SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.**

9 (a) AT-RISK INDIVIDUALS IN THE NATIONAL  
10 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)  
11 (42 U.S.C. 300hh–1(b)(4)(B)) is amended—

12 (1) by striking “this section and sections 319C–  
13 1, 319F, and 319L,” and inserting “this Act”; and

14 (2) by striking “special” and inserting “access  
15 or functional”.

16 (b) COUNTERMEASURE CONSIDERATIONS.—Section  
17 319L(e)(6) (42 U.S.C. 247d–7e(e)(6)) is amended—

18 (1) by striking “elderly” and inserting “senior  
19 citizens”; and

20 (2) by inserting “with relevant characteristics  
21 that warrant consideration during the process of re-  
22 searching and developing such countermeasures and  
23 products” before the period.

1 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**  
2 **RESPONSE CONSIDERATIONS FOR CHIL-**  
3 **DREN.**

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

6 **“SEC. 319D-1. CHILDREN’S PREPAREDNESS UNIT.**

7 “(a) **ENHANCING EMERGENCY PREPAREDNESS FOR**  
8 **CHILDREN.**—The Secretary, acting through the Director  
9 of the Centers for Disease Control and Prevention (re-  
10 ferred to in this subsection as the ‘Director’), shall main-  
11 tain an internal team of experts, to be known as the Chil-  
12 dren’s Preparedness Unit (referred to in this subsection  
13 as the ‘Unit’), to work collaboratively to provide guidance  
14 on the considerations for, and the specific needs of, chil-  
15 dren before, during, and after public health emergencies.  
16 The Unit shall inform the Director regarding emergency  
17 preparedness and response efforts pertaining to children  
18 at the Centers for Disease Control and Prevention.

19 “(b) **EXPERTISE.**—The team described in subsection  
20 (a) shall include one or more pediatricians, which may be  
21 a developmental-behavioral pediatrician, and may also in-  
22 clude behavioral scientists, child psychologists, epidemiolo-  
23 gists, biostatisticians, health communications staff, and  
24 individuals with other areas of expertise, as the Secretary  
25 determines appropriate.



1       “(c) DUTIES.—The team described in subsection (a)  
2 may—

3           “(1) assist State, local, tribal, and territorial  
4 emergency planning and response activities related  
5 to children, which may include developing, identi-  
6 fying, and sharing best practices;

7           “(2) provide technical assistance, training, and  
8 consultation to Federal, State, local, tribal, and ter-  
9 ritorial public health officials to improve prepared-  
10 ness and response capabilities with respect to the  
11 needs of children, including providing such technical  
12 assistance, training, and consultation to eligible enti-  
13 ties in order to support the achievement of measur-  
14 able evidence-based benchmarks and objective stand-  
15 ards applicable to sections 319C–1 and 319C–2 ;

16           “(3) improve the utilization of methods to in-  
17 corporate the needs of children in planning for and  
18 responding to a public health emergency, including  
19 public awareness of such methods;

20           “(4) coordinate with, and improve, public-pri-  
21 vate partnerships, such as health care coalitions pur-  
22 suant to sections 319C–2 and 319C–3, to address  
23 gaps and inefficiencies in emergency preparedness  
24 and response efforts for children;

1           “(5) provide expertise and input during the de-  
2           velopment of guidance and clinical recommendations  
3           to address the needs of children when preparing for,  
4           and responding to, public health emergencies, includ-  
5           ing pursuant to section 319C-3; and

6           “(6) carry out other duties related to prepared-  
7           ness and response activities for children, as the Sec-  
8           retary determines appropriate.”.

9 **SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COM-**  
10 **MITTEE ON CHILDREN AND DISASTERS.**

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

12           (1) in subsection (b)(2), by inserting “, mental  
13           and behavioral,” after “medical”;

14           (2) in subsection (d)—

15           (A) in paragraph (1), by striking “15” and  
16           inserting “25”; and

17           (B) by striking paragraph (2) and insert-  
18           ing the following:

19           “(2) **REQUIRED NON-FEDERAL MEMBERS.**—The  
20           Secretary, in consultation with such other heads of  
21           Federal agencies as may be appropriate, shall ap-  
22           point to the Advisory Committee under paragraph  
23           (1) at least 13 individuals to perform the duties de-  
24           scribed in subsections (b) and (c), including—

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

4           “(B) at least 2 representatives from State,  
5           local, tribal, or territorial agencies with exper-  
6           tise in pediatric disaster planning, prepared-  
7           ness, response, or recovery;

8           “(C) at least 4 members representing  
9           health care professionals, which may include  
10          members with expertise in pediatric emergency  
11          medicine; pediatric trauma, critical care, or sur-  
12          gery; the treatment of pediatric patients af-  
13          fected by chemical, biological, radiological, or  
14          nuclear agents and emerging infectious dis-  
15          eases; pediatric mental or behavioral health re-  
16          lated to children affected by a public health  
17          emergency; or pediatric primary care; and

18          “(D) other members as the Secretary de-  
19          termines appropriate, of whom—

20                  “(i) at least one such member shall  
21                  represent a children’s hospital;

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





1                   “(G) The Administrator of the Health Re-  
2                   sources and Services Administration.

3                   “(H) The Administrator of the Federal  
4                   Emergency Management Agency.

5                   “(I) The Administrator of the Administra-  
6                   tion for Community Living.

7                   “(J) The Secretary of Education.

8                   “(K) Representatives from such Federal  
9                   agencies (such as the Substance Abuse and  
10                  Mental Health Services Administration and the  
11                  Department of Homeland Security) as the Sec-  
12                  retary determines appropriate to fulfill the du-  
13                  ties of the Advisory Committee under sub-  
14                  sections (b) and (c).”.

15                  “(4) TERM OF APPOINTMENT.—Each member  
16                  of the Advisory Committee appointed under para-  
17                  graph (2) shall serve for a term of 3 years, except  
18                  that the Secretary may adjust the terms of the Advi-  
19                  sory Committee appointees serving on the date of  
20                  enactment of the Pandemic and All-Hazards Pre-  
21                  paredness and Advancing Innovation Act of 2018, or  
22                  appointees who are initially appointed after such  
23                  date of enactment, in order to provide for a stag-  
24                  gered term of appointment for all members.

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

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

9           (4) by redesignating subsection (f) as sub-  
10          section (g);

11          (5) by inserting after subsection (e) the fol-  
12          lowing:

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

16          (6) in subsection (g), as so redesignated, by  
17          striking “2018” and inserting “2023”.

18       **SEC. 306. AUTHORIZING THE NATIONAL ADVISORY COM-**  
19                               **MITTEE ON SENIORS AND DISASTERS.**

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

22       **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SEN-**  
23                               **IORS AND DISASTERS.**

24          “(a) ESTABLISHMENT.—The Secretary, in consulta-  
25          tion with the Secretary of Homeland Security and the Sec-

1   retary of Veterans Affairs, shall establish an advisory com-  
2   mittee to be known as the National Advisory Committee  
3   on Seniors and Disasters (referred to in this section as  
4   the ‘Advisory Committee’).

5       “(b) DUTIES.—

6           “(1) IN GENERAL.—The Advisory Committee  
7       shall—

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

11                   “(B) evaluate and provide input with re-  
12      spect to the medical and public health needs of  
13      seniors related to the preparation for, response  
14      to, and recovery from all-hazards emergencies;  
15      and

16                   “(C) provide advice and consultation with  
17      respect to State emergency preparedness and  
18      response activities and seniors, including related  
19      drills and exercises pursuant to the prepared-  
20      ness goals under section 2802(b).

21           “(2) ADDITIONAL DUTIES.—The Advisory Com-  
22      mittee may provide advice and recommendations to  
23      the Secretary with respect to seniors and the med-  
24      ical and public health grants and cooperative agree-

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

3           “(3) MEMBERSHIP.—

4               “(A) IN GENERAL.—The Secretary, in con-  
5       sultation with such other heads of agencies as  
6       appropriate, shall appoint not more than 15  
7       members to the Advisory Committee. In ap-  
8       pointing such members, the Secretary shall en-  
9       sure that the total membership of the Advisory  
10      Committee is an odd number.

11           “(B) REQUIRED MEMBERS.—The members  
12      appointed under paragraph (1) shall include—

13               “(i) the Assistant Secretary for Pre-  
14      paredness and Response;

15               “(ii) the Director of the Biomedical  
16      Advanced Research and Development Au-  
17      thority;

18               “(iii) the Director of the Centers for  
19      Disease Control and Prevention;

20               “(iv) the Commissioner of Food and  
21      Drugs;

22               “(v) the Director of the National In-  
23      stitutes of Health;

24               “(vi) the Administrator of the Centers  
25      for Medicare & Medicaid Services;

1                   “(vii) the Administrator of the Ad-  
2                   ministration for Community Living;

3                   “(viii) the Administrator of the Fed-  
4                   eral Emergency Management Agency;

5                   “(ix) the Under Secretary for Health  
6                   of the Department of Veterans Affairs;

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

11                  “(xi) at least 2 representatives of  
12                  State, local, territorial, or tribal agencies  
13                  with expertise in disaster planning, pre-  
14                  paredness, response, or recovery; and

15                  “(xii) representatives of such other  
16                  Federal agencies (such as the Department  
17                  of Energy and the Department of Home-  
18                  land Security) as the Secretary determines  
19                  necessary to fulfill the duties of the Advi-  
20                  sory Committee.

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

23                  “(d) ADVISORY COMMITTEE COORDINATION.—

24                  “(1) IN GENERAL.—The Secretary shall coordi-  
25                  nate activities authorized under this section and sec-

1       tion 2811A, and make efforts to reduce unnecessary  
2       or duplication of meetings, recommendations, and  
3       reporting under such sections. Members of the advi-  
4       sory committees under this section and section  
5       2811A, or their designees, shall meet periodically,  
6       and not less than annually, to—

7               “(A) review the recommendations devel-  
8               oped by such committees to coordinate, as ap-  
9               propriate, the implementation of recommenda-  
10              tions, in order to reduce gaps, overlap, and du-  
11              plication of effort in Federal programs or by  
12              Federal grantees; and

13              “(B) align preparedness and response pro-  
14              grams or activities to address the dual or over-  
15              lapping needs of children and seniors and any  
16              challenges in preparing for and responding to  
17              such needs.

18              “(2) NOTIFICATION.—The Secretary shall no-  
19              tify the congressional committees of jurisdiction  
20              upon the convening of each meeting under para-  
21              graph (1), and provide minutes from such meeting  
22              not later than 90 days after the meeting.

23              “(e) SUNSET.—The Advisory Committee shall termi-  
24              nate on September 30, 2023.”.

1 **SEC. 307. GUIDANCE FOR PARTICIPATION IN EXERCISES**  
2 **AND DRILLS.**

3 Not later than 2 years after the date of enactment  
4 of this Act, the Secretary of Health and Human Services  
5 shall issue final guidance regarding the participation of  
6 State, local, tribal, and territorial public health depart-  
7 ment or agency personnel funded in whole or in part  
8 through programs authorized under this Act in drills and  
9 operational exercises in order to identify, inform, and ad-  
10 dress the gaps in and policies related to all-hazards med-  
11 ical and public health preparedness and response, which  
12 may include drills and operational exercises that incor-  
13 porate medical surge capacity planning, medical counter-  
14 measure distribution and administration, and preparing  
15 for and responding to identified threats for that region.  
16 The Secretary shall consult with the Department of  
17 Homeland Security, the Department of Defense, the De-  
18 partment of Veterans Affairs, and other applicable Fed-  
19 eral departments and agencies as necessary and appro-  
20 priate in the development of such guidance. The Secretary  
21 shall make the guidance available on the internet website  
22 of the Department of Health and Human Services.



1           **TITLE IV—PRIORITIZING A**  
2           **THREAT-BASED APPROACH**

3   **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**  
4           **RESPONSE.**

5           Section 2811(b) (42 U.S.C. 300hh–10(b)) is amend-  
6 ed—

7           (1) in the matter preceding paragraph (1) by  
8 inserting “utilize experience related to public health  
9 emergency preparedness and response, biodefense,  
10 medical countermeasures, and other relevant topics  
11 to” after “shall”; and

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

14           “(I) THREAT AWARENESS.—Coordinate  
15 with the Director of the Centers for Disease  
16 Control and Prevention, the Director of Na-  
17 tional Intelligence, the Secretary of Homeland  
18 Security, the Assistant to the President for Na-  
19 tional Security Affairs, the Secretary of De-  
20 fense, and other relevant Federal officials, such  
21 as the Secretary of Agriculture, to maintain a  
22 current assessment of national security threats  
23 and inform preparedness and response capabili-  
24 ties based on the range of the threats that have

1 the potential to result in a public health emer-  
2 gency.”.

3 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**  
4 **TERMEASURES ENTERPRISE.**

5 (a) IN GENERAL.—Title XXVIII is amended by in-  
6 serting after section 2811 (42 U.S.C. 300hh–10) the fol-  
7 lowing:

8 **“SEC. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL**  
9 **COUNTERMEASURES ENTERPRISE.**

10 “(a) IN GENERAL.—The Secretary shall establish the  
11 Public Health Emergency Medical Countermeasures En-  
12 terprise (referred to in this section as the ‘PHEMCE’).  
13 The Assistant Secretary for Preparedness and Response  
14 shall serve as chair of the PHEMCE.

15 “(b) MEMBERS.—The PHEMCE shall include each  
16 of the following members, or the designee of such mem-  
17 bers:

18 “(1) The Assistant Secretary for Preparedness  
19 and Response.

20 “(2) The Director of the Centers for Disease  
21 Control and Prevention.

22 “(3) The Director of the National Institutes of  
23 Health.

24 “(4) The Commissioner of Food and Drugs.

25 “(5) The Secretary of Defense.

1 “(6) The Secretary of Homeland Security.

2 “(7) The Secretary of Agriculture.

3 “(8) The Secretary of Veterans Affairs.

4 “(9) Representatives of any other Federal agency,  
5 which may include the Director of the Bio-  
6 medical Advanced Research and Development Au-  
7 thority, the Director of the Strategic National Stock-  
8 pile, the Director of the National Institute of Allergy  
9 and Infectious Diseases, and the Director of the Of-  
10 fice of Public Health Preparedness and Response, as  
11 the Secretary determines appropriate.

12 “(c) FUNCTIONS.—

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

15 “(A) Establish a process pursuant to sec-  
16 tion 2811(d)(2)(B) to make recommendations  
17 to the Secretary regarding the prioritization of  
18 research, development, and procurement of  
19 countermeasures, as defined in section 319F-  
20 2(e), based on the health security needs of the  
21 United States. Such recommendations shall be  
22 informed by the National Health Security  
23 Strategy pursuant to section 2802, the Stra-  
24 tegic National Stockpile review required under  
25 section 319F-2(a)(2), the countermeasures

1 budget plan pursuant to section 2811(b)(7),  
2 and an assessment of current national security  
3 threats, including chemical, biological, radio-  
4 logical and nuclear threats, including emerging  
5 infectious diseases. In the event that members  
6 of the PHEMCE do not agree upon a rec-  
7 ommendation, the Secretary shall provide a de-  
8 termination regarding such recommendation.

9 “(B) Identify national health security  
10 needs, including gaps in public health prepared-  
11 ness and response related to countermeasures  
12 and challenges to addressing such needs (in-  
13 cluding any regulatory challenges), and provide  
14 for alignment of countermeasure procurement  
15 with recommendations under subparagraph (A).

16 “(C) Develop strategies related to logistics,  
17 deployment, distribution, dispensing, and use of  
18 countermeasures that may be applicable to the  
19 activities of the strategic national stockpile  
20 under section 319F-2(a).

21 “(D) Provide consultation for the develop-  
22 ment of the strategy and implementation plan  
23 under section 2811(d).

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

1 solicit and consider input from State, local, tribal,  
2 and territorial public health departments, as appro-  
3 priate.”.

4 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-  
5 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-  
6 TATION PLAN.—Section 2811(d) (42 U.S.C. 300hh-  
7 10(d)) is amended—

8 (1) in paragraph (1)—

9 (A) by striking “Not later than 180 days  
10 after the date of enactment of this subsection,  
11 and every year thereafter” and inserting “Not  
12 later than March 15, 2020, and biennially  
13 thereafter”; and

14 (B) by striking “Director of Biomedical”  
15 and all that follows through “Food and Drugs”  
16 and inserting “Public Health Emergency Med-  
17 ical Countermeasures Enterprise established  
18 under section 2811-1”; and

19 (2) in paragraph (2)(J)(v), by striking “one-  
20 year period” and inserting “2-year period”.

21 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

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

1 (2) in paragraph (1)—

2 (A) by inserting “and optimize” after  
3 “provide for”;

4 (B) by inserting “and, as informed by ex-  
5 isting recommendations of, or consultations  
6 with, the Public Health Emergency Medical  
7 Countermeasure Enterprise established under  
8 section 2811–1, make necessary additions or  
9 modifications to the contents of such stockpile  
10 or stockpiles based on the review conducted  
11 under paragraph (2)” before the period of the  
12 first sentence; and

13 (C) by striking the second sentence;

14 (3) by inserting after paragraph (1) the fol-  
15 lowing:

16 “(2) THREAT-BASED REVIEW.—

17 “(A) IN GENERAL.—The Secretary shall  
18 conduct an annual threat-based review (taking  
19 into account at-risk individuals) of the contents  
20 of the stockpile under paragraph (1), including  
21 non-pharmaceutical supplies, and, in consulta-  
22 tion with the Public Health Emergency Medical  
23 Countermeasures Enterprise established under  
24 section 2811–1, review contents within the  
25 stockpile and assess whether such contents are

1 consistent with the recommendations made pur-  
2 suant to section 2811–1(c)(1)(A). Such review  
3 shall be submitted annually, beginning on  
4 March 15, 2019, to the Committee on Health,  
5 Education, Labor, and Pensions and the Com-  
6 mittee on Appropriations of the Senate and the  
7 Committee on Energy and Commerce and the  
8 Committee on Appropriations of the House of  
9 Representatives, in a manner that does not  
10 compromise national security.

11 “(B) ADDITIONS, MODIFICATIONS, AND  
12 REPLENISHMENTS.—Each annual threat-based  
13 review under subparagraph (A) shall, for each  
14 new or modified countermeasure procurement  
15 or replenishment, provide—

16 “(i) information regarding—

17 “(I) the quantities of the addi-  
18 tional or modified countermeasure  
19 procured for, or contracted to be pro-  
20 cured for, the stockpile;

21 “(II) planning considerations for  
22 appropriate manufacturing capacity  
23 and capability to meet the goals of  
24 such additions or modifications (with-  
25 out disclosing proprietary informa-

1                   tion), including consideration of the  
2                   effect such additions or modifications  
3                   may have on the availability of such  
4                   products and ancillary medical sup-  
5                   plies in the health care system;

6                   “(III) the presence or lack of a  
7                   commercial market for the counter-  
8                   measure at the time of procurement;

9                   “(IV) the emergency health secu-  
10                  rity threat or threats such counter-  
11                  measure procurement is intended to  
12                  address, including whether such pro-  
13                  curement is consistent with meeting  
14                  emergency health security needs asso-  
15                  ciated with such threat or threats;

16                  “(V) an assessment of whether  
17                  the emergency health security threat  
18                  or threats described in subclause (IV)  
19                  could be addressed in a manner that  
20                  better utilizes the resources of the  
21                  stockpile and permits the greatest  
22                  possible increase in the level of emer-  
23                  gency preparedness to address such  
24                  threats;



1                   “(VI) whether such counter-  
2                   measure is replenishing an expired  
3                   countermeasure, is a different coun-  
4                   termeasure with the same indication  
5                   that is replacing an expired counter-  
6                   measure, or is a new addition to the  
7                   stockpile;

8                   “(VII) a description of how such  
9                   additions or modifications align with  
10                  the countermeasures budget plan as  
11                  required under section 2811(b)(7), in-  
12                  cluding expected life-cycle costs, ex-  
13                  penditures related to countermeasure  
14                  procurement to address the threat or  
15                  threats described in subclause (IV),  
16                  replenishment dates (including the  
17                  ability to extend the maximum shelf  
18                  life of a countermeasure), and the  
19                  manufacturing capacity required to  
20                  replenish such countermeasure; and

21                  “(VIII) appropriate protocols and  
22                  processes for the deployment, distribu-  
23                  tion, or dispensing of the counter-  
24                  measure at the State and local level,  
25                  including plans for relevant capabili-

1                   ties of State and local entities to dis-  
2                   pense, distribute, and administer the  
3                   countermeasure; and

4                   “(ii) an assurance that for each coun-  
5                   termeasure produced or replenished under  
6                   this subsection, the Secretary completed a  
7                   review addressing each item listed under  
8                   this subsection in advance of such procure-  
9                   ment or replenishment, which need not be  
10                  provided in advance of procurement.”;

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

12                   (A) in subparagraph (A), by inserting  
13                   “and the Public Health Emergency Medical  
14                   Countermeasures Enterprise established under  
15                   section 2811-1” before the semicolon;

16                   (B) in subparagraph (C), by inserting “,  
17                   and the availability, deployment, dispensing,  
18                   and administration of countermeasures” before  
19                   the semicolon; and

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

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

1 ant Secretary for Preparedness and Response,  
2 the Secretary of Transportation, the Secretary  
3 of Homeland Security, the Secretary of Vet-  
4 erans Affairs, and the heads of other appro-  
5 priate Federal agencies, State, local, tribal, and  
6 territorial agencies, and the public and private  
7 health care infrastructure, as applicable, taking  
8 into account the manufacturing capacity and  
9 other available sources of products and appro-  
10 priate alternatives to supplies in the stockpile;”  
11 and

12 (5) by adding at the end the following:

13 “(5) GAO REPORT.—

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

23 “(i) an assessment of the comprehen-  
24 siveness and completeness of each annual  
25 threat-based review under paragraph (2),

1 including whether all newly procured or re-  
2 plenished countermeasures within the  
3 stockpile were described in each annual re-  
4 view, and whether, consistent with para-  
5 graph (2)(B), the Secretary conducted the  
6 necessary internal review in advance of  
7 such procurement or replenishment;

8 “(ii) an assessment of whether the  
9 Secretary established health security and  
10 science-based justifications, and a descrip-  
11 tion of such justifications for procurement  
12 decisions related to health security needs  
13 with respect to the identified threat, for  
14 additions or modifications to the stockpile  
15 based on the information provided in such  
16 reviews under paragraph (2)(B), including  
17 whether such review was conducted prior  
18 to procurement, modification, or replenish-  
19 ment;

20 “(iii) an assessment of the plans de-  
21 veloped by the Secretary for the deploy-  
22 ment, distribution, and dispensing of coun-  
23 termeasures procured, modified, or replen-  
24 ished under paragraph (1), including  
25 whether such plans were developed prior to

1 procurement, modification, or replenish-  
2 ment;

3 “(iv) an accounting of counter-  
4 measures procured, modified, or replen-  
5 ished under paragraph (1) that received  
6 advanced research and development fund-  
7 ing from the Biomedical Advanced Re-  
8 search and Development Authority;

9 “(v) an analysis of how such procure-  
10 ment decisions made progress towards  
11 meeting emergency health security needs  
12 related to the identified threats for coun-  
13 termeasures added, modified, or replen-  
14 ished under paragraph (1);

15 “(vi) a description of the resources ex-  
16 pended related to the procurement of coun-  
17 termeasures (including additions, modifica-  
18 tions, and replenishments) in the stockpile,  
19 and how such expenditures relate to the  
20 emergency health security needs of the  
21 stockpile;

22 “(vii) an assessment of the extent to  
23 which additions, modifications, and replen-  
24 ishments reviewed under paragraph (2)  
25 align with previous relevant reports or re-

1 views by the Secretary or the Comptroller  
2 General; and

3 “(viii) with respect to any change in  
4 the Federal organizational management of  
5 the stockpile, an assessment and compari-  
6 son of the processes affected by such  
7 change, including planning for potential  
8 countermeasure deployment, distribution,  
9 or dispensing capabilities and processes re-  
10 lated to procurement decisions, use of  
11 stockpiled countermeasures, and use of re-  
12 sources for such activities.

13 “(B) SUBMISSION.—Not later than 6  
14 months after completing a classified version of  
15 the review under subparagraph (A), the Comp-  
16 troller General shall submit an unclassified  
17 version of the review to the congressional com-  
18 mittees of jurisdiction.”.

19 (b) AUTHORIZATION OF APPROPRIATIONS, STRA-  
20 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42  
21 U.S.C. 247d–6b(f)(1)) is amended by striking  
22 “\$533,800,000 for each of fiscal years 2014 through  
23 2018” and inserting “\$610,000,000 for each of fiscal  
24 years 2019 through 2023”.

1 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**  
2 **MICROBIAL RESISTANCE, AND OTHER SIG-**  
3 **NIFICANT THREATS.**

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

6 “(F) STRATEGIC INITIATIVES.—The Sec-  
7 retary, acting through the Director of BARDA,  
8 may implement strategic initiatives, including  
9 by building on existing programs and by award-  
10 ing grants supporting innovative candidate  
11 products in preclinical and clinical development,  
12 to address priority, naturally occurring and  
13 man-made threats that, as determined by the  
14 Secretary, pose a significant level of risk to na-  
15 tional security based on the characteristics of a  
16 chemical, biological, radiological or nuclear  
17 threat, or existing capabilities to respond to  
18 such a threat (including medical response and  
19 treatment capabilities and manufacturing infra-  
20 structure). Such initiatives shall accelerate and  
21 support the advanced research, development,  
22 and procurement of, countermeasures and prod-  
23 ucts, as applicable, to address areas including—  
24 “(i) chemical, biological, radiological,  
25 or nuclear threats, including emerging in-  
26 fectious diseases, for which insufficient ap-

1           proved, licensed, or authorized counter-  
2           measures exist, or for which such threat,  
3           or the result of an exposure to such threat,  
4           may become resistant to countermeasures  
5           or existing countermeasures may be ren-  
6           dered ineffective;

7           “(ii) threats that consistently exist or  
8           continually circulate and have significant  
9           potential to become a pandemic, such as  
10          pandemic influenza, which may include the  
11          advanced research and development, manu-  
12          facturing, and appropriate stockpiling of  
13          qualified pandemic or epidemic products,  
14          and products, technologies, or processes to  
15          support the advanced research and devel-  
16          opment of such countermeasures (including  
17          multiuse platform technologies for  
18          diagnostics, vaccines, and therapeutics;  
19          virus seeds; clinical trial lots; novel virus  
20          strains; and antigen and adjuvant mate-  
21          rial); and

22          “(iii) threats that may result pri-  
23          marily or secondarily from a chemical, bio-  
24          logical, radiological, or nuclear agent, or  
25          emerging infectious disease, and which



1                   may present increased treatment complica-  
2                   tions such as the occurrence of resistance  
3                   to available countermeasures or potential  
4                   countermeasures, including antimicrobial  
5                   resistant pathogens.”.

6 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**  
7                   **PROGRAM.**

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

9                   (1) by striking “The Secretary” and inserting  
10                  the following:

11                  “(1) IN GENERAL.—The Secretary”; and

12                  (2) by adding at the end the following:

13                  “(2) IMPLEMENTATION OF RECOMMENDATIONS  
14                  OF THE FEDERAL EXPERTS SECURITY ADVISORY  
15                  PANEL AND THE FAST TRACK ACTION COMMITTEE  
16                  ON SELECT AGENT REGULATIONS.—

17                  “(A) IN GENERAL.—Not later than 1 year  
18                  after the date of the enactment of the Pan-  
19                  demic and All-Hazards Preparedness and Ad-  
20                  vancing Innovation Act of 2018, the Secretary  
21                  shall report to the congressional committees of  
22                  jurisdiction on the implementation of rec-  
23                  ommendations of the Federal Experts Security  
24                  Advisory Panel concerning the select agent pro-  
25                  gram.

1           “(B) CONTINUED UPDATES.—The Sec-  
2           retary shall report to the congressional commit-  
3           tees of jurisdiction annually following the sub-  
4           mission of the report under subparagraph (A)  
5           until the recommendations described in such  
6           subparagraph are fully implemented, or a jus-  
7           tification is provided for the delay in, or lack of,  
8           implementation.”.

9   **TITLE V—INCREASING COMMU-**  
10   **NICATION IN MEDICAL COUN-**  
11   **TERMEASURE ADVANCED RE-**  
12   **SEARCH AND DEVELOPMENT**

13   **SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.**

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

16           (1) in the matter preceding subparagraph (A),  
17   by striking “March 1” and inserting “March 15”;

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

20           “(A) include consideration of the entire  
21   medical countermeasures enterprise, includ-  
22   ing—

23           “(i) basic research and advanced re-  
24   search and development;

1                   “(ii) approval, clearance, licensure,  
2                   and authorized uses of products;

3                   “(iii) procurement, stockpiling, main-  
4                   tenance, and potential replenishment (in-  
5                   cluding manufacturing capabilities) of all  
6                   products in the Strategic National Stock-  
7                   pile; and

8                   “(iv) the availability of technologies  
9                   that may assist in the advanced research  
10                  and development of countermeasures and  
11                  opportunities to use such technologies to  
12                  accelerate and navigate challenges unique  
13                  to countermeasure research and develop-  
14                  ment;”.

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

17                  (4) by inserting after subparagraph (C), the fol-  
18                  lowing:

19                  “(D) identify the full range of anticipated  
20                  medical countermeasure needs related to re-  
21                  search and development, procurement, and  
22                  stockpiling, including the potential need for in-  
23                  dications, dosing, and administration tech-  
24                  nologies, and other countermeasure needs as  
25                  applicable and appropriate;”.

1 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**  
2 **MEASURE NOTIFICATIONS.**

3 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL  
4 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42  
5 U.S.C. 247d–6b(c)(2)(C)) is amended by striking “The  
6 Secretary and the Homeland Security Secretary shall  
7 promptly notify the appropriate committees of Congress”  
8 and inserting “The Secretary and the Secretary of Home-  
9 land Security shall send to Congress, on an annual basis,  
10 all current material threat determinations and shall  
11 promptly notify the Committee on Health, Education,  
12 Labor, and Pensions and the Committee on Homeland Se-  
13 curity and Government Affairs of the Senate and the Com-  
14 mittee on Energy and Commerce and the Committee on  
15 Homeland Security of the House of Representatives”.

16 (b) CONTRACTING COMMUNICATIONS.—

17 (1) CONTRACT DURATION.—Section 319F–  
18 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–  
19 6b(c)(7)(B)(ii)(III)) is amended by adding at the  
20 end the following: “The Secretary shall notify the  
21 vendor within 90 days of a determination by the  
22 Secretary to renew such contract.”.

23 (2) EXPEDITED AUTHORITIES.—Section  
24 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is  
25 amended by adding at the end the following: “Upon  
26 award, extension, or termination of any such con-

1       tract, grant, cooperative agreement, and other trans-  
2       action, the Secretary shall provide a written notifica-  
3       tion to the receiving entity that includes a justifica-  
4       tion for such award, extension, or termination.”.

5       **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**  
6                                   **PLANS.**

7       Section 565(f) of the Federal Food, Drug and Cos-  
8       metic Act (21 U.S.C. 360bbb-4(f)) is amended—

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

11             (2) by inserting after paragraph (2) the fol-  
12             lowing:

13             “(3) PUBLICATION.—The Secretary shall make  
14             available on the internet website of the Food and  
15             Drug Administration information regarding regu-  
16             latory management plans, including—

17               “(A) the process by which an applicant  
18               may submit a request for a regulatory manage-  
19               ment plan;

20               “(B) the timeframe by which the Secretary  
21               is required to respond to such request;

22               “(C) the information required for the sub-  
23               mission of such request;

24               “(D) a description of the types of develop-  
25               ment milestones and performance targets that

1 could be discussed and included in such plans;

2 and

3 “(E) contact information for beginning the  
4 regulatory management plan process.”;

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

7 (A) by striking “paragraph (4)(A)” and in-  
8 serting “paragraph (5)(A)”; and

9 (B) by striking “paragraph (4)(B)” and  
10 inserting “paragraph (5)(B)”; and

11 (4) in paragraph (7)(A), as so redesignated, by  
12 striking “paragraph (3)(A)” and inserting “para-  
13 graph (4)(A)”.

14 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**  
15 **VELOPMENT AUTHORITY AND THE BIO-**  
16 **SHIELD SPECIAL RESERVE FUND.**

17 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section  
18 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

19 (1) by striking “\$2,800,000,000 for the period  
20 of fiscal years 2014 through 2018” and inserting  
21 “\$3,500,000,000 for the period of fiscal years 2019  
22 through 2023, to remain available until expended”;  
23 and

24 (2) by striking the second sentence.



1 (b) THE BIOMEDICAL ADVANCED RESEARCH AND  
2 DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42  
3 U.S.C. 247d–7e(d)(2)) is amended by striking  
4 “\$415,000,000 for each of fiscal years 2014 through  
5 2018” and inserting “\$611,700,000 for each of fiscal  
6 years 2019 through 2023”.

7 **TITLE VI—ADVANCING TECH-**  
8 **NOLOGIES FOR MEDICAL**  
9 **COUNTERMEASURES**

10 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

11 Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–  
12 7e(c)(4)(D)(iii)) is amended by striking “and platform  
13 technologies” inserting “platform technologies, tech-  
14 nologies to administer countermeasures, and technologies  
15 to improve storage and transportation of counter-  
16 measures”.

17 **SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.**

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

21 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

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

1 tating and encouraging submission of data and informa-  
2 tion to support such products to master files, and through  
3 clarifying the authority to cross-reference to data and in-  
4 formation previously submitted to the Secretary.

5 “(b) APPLICABILITY OF REFERENCE.—

6 “(1) IN GENERAL.—A person may submit data  
7 and information to the Secretary with the intent to  
8 reference, or to authorize, in writing, another person  
9 to reference, such data or information to support a  
10 medical countermeasure submission (including a  
11 supplement or amendment to any such submission),  
12 without requiring the master file holder to disclose  
13 the data and information to any such persons au-  
14 thorized to reference the master file. Such data and  
15 information shall be available for reference by the  
16 master file holder or a person authorized by the  
17 master file holder only in accordance with applicable  
18 privacy and confidentiality protocols and regulations.

19 “(2) MASTER FILE HOLDER.—In this section,  
20 the term ‘master file holder’ means a person who  
21 submits data and information to the Secretary with  
22 the intent to reference or authorize to reference such  
23 data or information to support a medical counter-  
24 measure submission, as described in paragraph (1).



1       “(c) MEDICAL COUNTERMEASURE MASTER FILE  
2 CONTENT.—

3           “(1) IN GENERAL.—A master file under this  
4 section may include information to support and ac-  
5 celerate—

6           “(A) the development of medical counter-  
7 measure submissions to support the approval,  
8 licensure, classification, clearance, conditional  
9 approval, or authorization of one or more secu-  
10 rity countermeasures, qualified counter-  
11 measures, or qualified pandemic or epidemic  
12 products; and

13           “(B) the manufacture of security counter-  
14 measures, qualified countermeasures, or quali-  
15 fied pandemic or epidemic products.

16           “(2) REQUIRED UPDATES.—The Secretary may  
17 require, as appropriate, that the master file holder  
18 ensure that the contents of such master file are up-  
19 dated during the time such master file is referenced  
20 for a medical countermeasure submission.

21       “(d) SPONSOR REFERENCE.—

22           “(1) IN GENERAL.—Each incorporation of in-  
23 formation or data contained in a master file by ref-  
24 erence shall describe the incorporated material in a  
25 manner in which the Secretary determines appro-

1        appropriate and that permits the review of such informa-  
2        tion without necessitating resubmission of such in-  
3        formation or data. Master files shall be submitted in  
4        an electronic format in accordance with section  
5        745A and as specified in applicable guidance.

6            “(2) REFERENCE BY A MASTER FILE HOLD-  
7        ER.—A master file holder that is the sponsor of a  
8        medical countermeasure submission shall notify the  
9        Secretary in writing of the intent to reference the  
10       medical countermeasure master file as a part of the  
11       submission.

12           “(3) REFERENCE BY AN AUTHORIZED PER-  
13        SON.—A sponsor of a medical countermeasure sub-  
14        mission may, where the Secretary determines appro-  
15        priate, incorporate by reference all or part of the  
16        contents of a medical countermeasure master file, if  
17        the master file holder authorizes the incorporation in  
18        writing.

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

1 fied information or data to support the approval, classi-  
2 fication, conditional approval, clearance, licensure, or au-  
3 thorization of a security countermeasure, qualified coun-  
4 termeasure, or qualified pandemic or epidemic product.  
5 The Secretary may rely upon the data and information  
6 within the medical countermeasure master file for which  
7 such written notification was provided in additional appli-  
8 cations, as applicable and appropriate and upon the re-  
9 quest of the master file holder so notified in writing or  
10 by an authorized person of such holder.

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

13 “(1) alter the authority of the Secretary to ap-  
14 prove, license, classify, clear, conditionally approve,  
15 or authorize drugs, biological products, or devices  
16 pursuant to this Act or section 351 of the Public  
17 Health Service Act (as authorized prior to the date  
18 of enactment of the Pandemic and All-Hazards Pre-  
19 paredness and Advancing Innovation Act of 2018),  
20 including the standards of evidence, and applicable  
21 conditions, for approval under the applicable Act; or

22 “(2) alter the authority of the Secretary under  
23 this Act or the Public Health Service Act to deter-  
24 mine the types of information or data previously  
25 submitted by a sponsor or any other person that

1       may be incorporated by reference in an application,  
2       request, or notification for a drug, biological prod-  
3       uct, or device submitted under sections 505(i),  
4       505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571,  
5       520(g), 515(c), 513(f)(2), or 510(k) of this Act, or  
6       subsection (a) or (k) of section 351 of the Public  
7       Health Service Act, including a supplement or  
8       amendment to any such submission, and the require-  
9       ments associated with such reference.

10       “(g) DEFINITIONS.—In this section:

11               “(1) The term ‘medical countermeasure submis-  
12               sion’ means an investigational new drug application  
13               under section 505(i), a new drug application under  
14               section 505(b), or an abbreviated new drug applica-  
15               tion under section 505(j) of this Act, a biological  
16               product license application under section 351(a) of  
17               the Public Health Service Act or a biosimilar biologi-  
18               cal product license application under section 351(k)  
19               of the Public Health Service Act, a new animal drug  
20               application under section 512(b)(1) or abbreviated  
21               new animal drug application under section  
22               512(b)(2), an application for conditional approval of  
23               a new animal drug under 571, an investigational de-  
24               vice application under section 520(g), an application  
25               with respect to a device under section 515(c), a re-



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

5               “(A) the approval, licensure, classification,  
6               clearance, conditional approval, or authorization  
7               of a security countermeasure, qualified counter-  
8               measure, or qualified pandemic or epidemic  
9               product; or

10              “(B) a new indication to an approved secu-  
11              rity countermeasure, qualified countermeasure,  
12              or qualified pandemic or epidemic product.

13              “(2) The terms ‘qualified countermeasure’, ‘se-  
14              curity countermeasure’, and ‘qualified pandemic or  
15              epidemic product’ have the meanings given such  
16              terms in sections 319F-1, 319F-2, and 319F-3, re-  
17              spectively, of the Public Health Service Act.”.

18       (b) **STAKEHOLDER INPUT.**—Not later than 18  
19 months after the date of enactment of this Act, the Sec-  
20 retary of Health and Human Services (referred to in this  
21 section as the “Secretary”), acting through the Commis-  
22 sioner of Food and Drugs and in consultation with the  
23 Assistant Secretary for Preparedness and Response, shall  
24 solicit input from stakeholders, including stakeholders de-  
25 veloping security countermeasures, qualified counter-

1 measures, or qualified pandemic or epidemic products, and  
2 stakeholders developing technologies to assist in the devel-  
3 opment of such countermeasures with respect to how the  
4 Food and Drug Administration can advance the use of  
5 tools and technologies to support and accelerate the devel-  
6 opment or manufacture of security countermeasures,  
7 qualified countermeasures, and qualified pandemic or epi-  
8 demic products, including through the reliance on cross-  
9 referenced data and information contained within master  
10 files and submissions previously submitted to the Sec-  
11 retary as set forth in section 565B of the Federal Food,  
12 Drug, and Cosmetic Act, as added by subsection (a).

13 (c) GUIDANCE.—Not later than 2 years after the  
14 after the date of enactment of this Act, the Secretary, act-  
15 ing through the Commissioner of Food and Drugs, shall  
16 publish draft guidance about how reliance on cross-ref-  
17 erenced data and information contained within master  
18 files under section 565B of the Federal Food, Drug, and  
19 Cosmetic Act, as added by subsection (a) or submissions  
20 otherwise submitted to the Secretary may be used for spe-  
21 cific tools or technologies (including platform technologies)  
22 that have the potential to support and accelerate the devel-  
23 opment or manufacture of security countermeasures,  
24 qualified countermeasures, qualified pandemic or epidemic  
25 products. The Secretary, acting through the Commissioner

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

3 **SEC. 603. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

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

7 **“SEC. 512A. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

8 “(a) DESIGNATION OF A NEW ANIMAL DRUG AS A  
9 PRIORITY ZOO NOTIC ANIMAL DRUG.—

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

23 “(2) REQUEST FOR DESIGNATION.—The spon-  
24 sor of a new animal drug may request the Secretary  
25 to designate a new animal drug described in para-

1 graph (1) as a priority zoonotic animal drug. A re-  
2 quest for the designation may be made concurrently  
3 with, or at any time after, the opening of an inves-  
4 tigational new animal drug file under section 512(j)  
5 or the filing of an application under section  
6 512(b)(1) or 571.

7 “(3) DESIGNATION.—

8 “(A) IN GENERAL.—Not later than 60 cal-  
9 endar days after the receipt of a request under  
10 paragraph (2), the Secretary shall determine  
11 whether the new animal drug that is the subject  
12 of the request meets the criteria described in  
13 paragraph (1). If the Secretary determines that  
14 the new animal drug meets the criteria, the  
15 Secretary shall designate the new animal drug  
16 as a priority zoonotic animal drug and shall  
17 take such actions as are appropriate to expedite  
18 the development and review of the application  
19 for approval or conditional approval of such  
20 new animal drug.

21 “(B) ACTIONS.—The actions to expedite  
22 the development and review of an application  
23 under subparagraph (A) may include, as appro-  
24 priate—



1                   “(i) taking steps to ensure that the  
2                   design of clinical trials is as efficient as  
3                   practicable, when scientifically appropriate,  
4                   such as by utilizing novel trial designs or  
5                   drug development tools (including biomark-  
6                   ers) that may reduce the number of ani-  
7                   mals needed for studies;

8                   “(ii) providing timely advice to, and  
9                   interactive communication with, the spon-  
10                  sor (which may include meetings with the  
11                  sponsor and review team) regarding the  
12                  development of the new animal drug to en-  
13                  sure that the development program to  
14                  gather the nonclinical and clinical data  
15                  necessary for approval is as efficient as  
16                  practicable;

17                  “(iii) involving senior managers and  
18                  review staff with experience in zoonotic or  
19                  vector-borne disease to facilitate collabo-  
20                  rative, cross-disciplinary review, including,  
21                  as appropriate, across agency centers; and

22                  “(iv) implementing additional admin-  
23                  istrative or process enhancements, as nec-  
24                  essary, to facilitate an efficient review and  
25                  development program.”.

1 **SEC. 604. ANIMAL RULE REPORT.**

2 (a) STUDY.—The Comptroller General of the United  
3 States shall conduct a study on the application of the re-  
4 quirements under section 565(d) of the of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d))  
6 (referred to in this section as the “animal rule”) as a com-  
7 ponent of medical countermeasure advanced development  
8 under the Biomedical Advanced Research and Develop-  
9 ment Authority and regulatory review by the Food and  
10 Drug Administration. In conducting such study, the  
11 Comptroller General shall examine the following:

12 (1) The extent to which advanced development  
13 and review of a medical countermeasure are coordi-  
14 nated between the Biomedical Advanced Research  
15 and Development Authority and the Food and Drug  
16 Administration, including activities facilitate appro-  
17 priate and efficient design of studies to support ap-  
18 proval, licensure, and authorization under the ani-  
19 mal rule, consistent with the recommendations in the  
20 animal rule guidance, issued pursuant to section  
21 565(c) of the Federal Food Drug and Cosmetic Act  
22 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-  
23 velopment Under the Animal Rule Guidance for In-  
24 dustry” (issued in October 2015), to resolve discrep-  
25 ancies in the design of adequate and well-controlled  
26 efficacy studies conducted in animal models related

1 to the provision of substantial evidence of effective-  
2 ness for the product approved, licensed, or author-  
3 ized under the animal rule.

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

7 (3) The flexibilities pursuant to the animal rule  
8 to address variations in countermeasure development  
9 and review processes, including the extent to which  
10 qualified animal models are adopted and used within  
11 the Food and Drug Administration in regulatory de-  
12 cisionmaking with respect to medical counter-  
13 measures.

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

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

24 (1) the Federal agencies responsible for advanc-  
25 ing, reviewing, and procuring medical counter-



1 measures, including the Office of the Assistant Sec-  
2 retary for Preparedness and Response, the Bio-  
3 medical Advanced Research and Development Au-  
4 thority, the Food and Drug Administration, and the  
5 Department of Defense;

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

10 (3) other biodefense stakeholders, as applicable.

11 (c) REPORT.—Not later than 3 years after the date  
12 of enactment of this Act, the Comptroller General of the  
13 United States shall submit to the Committee on Health,  
14 Education, Labor, and Pensions of the Senate and the  
15 Committee on Energy and Commerce of the House of  
16 Representatives a report containing the results of the  
17 study conducted under subsection (a) and recommenda-  
18 tions to improve the application and consistency of the re-  
19 quirements under subsections (c) and (d) of section 565  
20 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.  
21 360bbb-4) to support and expedite the research and devel-  
22 opment of medical countermeasures, as applicable.

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

1 section in a manner that does not compromise national  
2 security.

3 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**  
4 **NEERING TECHNOLOGIES AND THEIR POTEN-**  
5 **TIAL ROLE IN NATIONAL SECURITY.**

6 (a) MEETING.—

7 (1) IN GENERAL.—Not later than 1 year after  
8 the date of enactment of this Act, the Secretary of  
9 Health and Human Services (referred to in this sec-  
10 tion as the “Secretary”) shall convene a meeting to  
11 discuss the potential role advancements in genomic  
12 engineering technologies (including genome editing  
13 technologies) may have in advancing national health  
14 security. Such meeting shall be held in a manner  
15 that does not compromise national security.

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

18 (A) shall include—

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

1 (ii) representatives from academic,  
2 private, and non-profit entities with exper-  
3 tise in genome engineering technologies,  
4 biopharmaceuticals, medicine, or bio-  
5 defense, and other relevant stakeholders;  
6 and

7 (B) may include—

8 (i) other representatives from the De-  
9 partment of Health and Human Services,  
10 as the Secretary determines appropriate;  
11 and

12 (ii) representatives from the Depart-  
13 ment of Homeland Security, the Depart-  
14 ment of Defense, the Department of Agri-  
15 culture, and other departments, as the Sec-  
16 retary may request for the meeting.

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

19 (A) the current state of the science of  
20 genomic engineering technologies related to na-  
21 tional health security, including—

22 (i) medical countermeasure develop-  
23 ment, including potential efficiencies in the  
24 development pathway and detection tech-  
25 nologies; and

1 (ii) the international and domestic  
2 regulation of products utilizing genome ed-  
3 iting technologies; and

4 (B) national security implications, includ-  
5 ing—

6 (i) capabilities of the United States to  
7 leverage genomic engineering technologies  
8 as a part of the medical countermeasure  
9 enterprise, including current applicable re-  
10 search, development, and application ef-  
11 forts underway within the Department of  
12 Defense;

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

17 (iii) security measures to monitor and  
18 assess the potential threat of genomic engi-  
19 neering technologies and related tech-  
20 nologies.

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

1 ommendations, as applicable, to utilize innovations in  
2 genomic engineering (including genome editing) and re-  
3 lated technologies as a part of preparedness and response  
4 activities to advance national health security. Such report  
5 shall be issued in a manner that does not compromise na-  
6 tional security.

7       **TITLE VII—MISCELLANEOUS**  
8                                   **PROVISIONS**

9       **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

10       (a) **VETERANS AFFAIRS.**—Section 8117(g) of title  
11 38, United States Code, is amended by striking “2014  
12 through 2018” and inserting “2019 through 2023”.

13       (b) **VACCINE TRACKING AND DISTRIBUTION.**—Sec-  
14 tion 319A(e) (42 U.S.C. 247d–1(e)) is amended by strik-  
15 ing “2014 through 2018” and inserting “2019 through  
16 2023”.

17       (c) **TEMPORARY REASSIGNMENT.**—Section 319(e)(8)  
18 (42 U.S.C. 247d(e)(8)) is amended by striking “2018”  
19 and inserting “2023”.

20       (d) **STRATEGIC INNOVATION PARTNER.**—Section  
21 319L(e)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is  
22 amended by striking “2022” and inserting “2023”.

23       (e) **PUBLIC DISCLOSURE EXEMPTION.**—Section  
24 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended  
25 by striking “12” and inserting “17”.



1 (f) LIMITED ANTITRUST EXEMPTION.—

2 (1) IN GENERAL.—Section 405 of the Pandemic  
3 and All-Hazards Preparedness Act (42 U.S.C.  
4 247d–6a note) is amended—

5 (A) by redesignating such section as sec-  
6 tion 319L–1;

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

11 (C) in subsection (a)(1)—

12 (i) by striking “Secretary of Health  
13 and Human Services (referred to in this  
14 subsection as the ‘Secretary’)” and insert-  
15 ing “Secretary”;

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

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

22 (iv) by striking “of the Public Health  
23 Service Act (42 U.S.C. 247d–6d)”;

24 (D) in subsection (b), by striking “12-  
25 year” and inserting “17-year”.

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

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

8 **SEC. 702. TECHNICAL AMENDMENTS.**

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

11           (1) in paragraphs (1) and (5) of section 319F–  
12           1(a) (42 U.S.C. 247d–6a(a)), by striking “section  
13           319F(h)” each place such term appears and insert-  
14           ing “section 319F(e)”; and

15           (2) in section 319K(a) (42 U.S.C. 247d–7d(a)),  
16           by striking “section 319F(h)(4)” and inserting “sec-  
17           tion 319F(e)(4)”.

18           (b) **PUBLIC HEALTH SECURITY GRANTS.**—Section  
19 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

20           (1) in subparagraph (C), by striking “individ-  
21           uals,,” and inserting “individuals,”; and

22           (2) in subparagraph (F), by striking “make sat-  
23           isfactory annual improvement and describe” and in-  
24           serting “makes satisfactory annual improvement and  
25           describes”.

1 (c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

2 The Federal Food, Drug, and Cosmetic Act is amended—

3 (1) in section 564A(e)(2)(A) (21 U.S.C.

4 360bbb-3a(e)(2)(A)), by striking “subsection

5 (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”;

6 and

7 (2) in section 564B(2)(C) (21 U.S.C. 360bbb-

8 3b(2)(C)), by inserting “or section 564A”.