115TH CONGRESS
2D SESSION

H. R. 7328

AN ACT

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, to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved drug application, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

DIVISION A—PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION

SEC. 100. REFERENCES IN DIVISION.

Except as otherwise specified—

(1) amendments made by this division to a section or other provision of law are amendments to such section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.); and

(2) any reference to ''this Act'' contained in this division shall be treated as referring only to the provisions of this division.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

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

(1) in subsection (a)—

(A) in paragraph (1)—

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

(ii) by striking the second sentence and inserting the following: ''Such Na-

tional Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with the national preparedness goal (as described in section 504(a)(19) of the Homeland Security Act of 2002), the National Incident Management System (as defined in section 501(7) of such Act), and the National Response Plan developed pursuant to section 504 of such Act, or any successor plan.'';

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

(C) in paragraph (3)—

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

(ii) by inserting ''(including gaps in the environmental health and animal

health workforces, as applicable), describing the status of such workforce'' after ''gaps in such workforce'';

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

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

(2) in subsection (b)—

(A) in paragraph (2)—

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

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

(iii) by adding at the end the following:

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

(B) in paragraph (3)—

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

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

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

(D) by adding at the end the following:

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

rectly related to public health emergency preparedness and response capabilities, as applicable.

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

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

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

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

''(k) EVALUATION.—

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

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

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

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

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

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

''(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accurately assess the ability of entities receiving

awards under this section to better achieve the goals under this section and section 2802.''.

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

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS.

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

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

(2) in subsection (b)(2)(A)—

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

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

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

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

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

(E) by adding at the end the following:

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

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

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

(1) IN GENERAL.—Section 319C–1(g) (42 U.S.C. 247d–3a(g)) is amended—

(A) in paragraph (5)—

(i) in the matter preceding subparagraph (A), by striking ''Beginning with fiscal year 2009'' and inserting ''Beginning with fiscal year 2019''; and

(ii) in subparagraph (A)—

(I) by striking ''for the immediately preceding fiscal year'' and inserting ''for either of the 2 immediately preceding fiscal years''; and

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

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

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

''(i) For no more than 1 of each of the first 2 fiscal years immediately fol-

lowing a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5), an amount equal to 10 percent of the amount the entity was eligible to receive for the respective fiscal year.

''(ii) For no more than 1 of the first 2 fiscal years immediately following the third consecutive fiscal year in which an entity experienced such a failure, in lieu of applying clause (i), an amount equal to 15 percent of the amount the entity was eligible to receive for the respective fiscal year.''.

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

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

(1) in subsection (a)—

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

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

(2) in subsection (b)(1)(A)—

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

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

(C) by adding at the end the following:

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

(3) in subsection (d)—

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

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

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

(5) in subsection (g)(2)—

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

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

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

(6) in subsection (i)(1)—

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

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

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

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

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

''(1) IN GENERAL.—

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

''(B) RESERVATION OF AMOUNTS FOR REGIONAL SYSTEMS.—

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

''(ii) RESERVATION CONTINGENT ON CONTINUED APPROPRIATIONS FOR THIS SECTION.—If for fiscal year 2019 or a subsequent fiscal year, the amount appropriated under subparagraph (A) is such that, after application of clause (i), the amount remaining for the purpose of carrying out this section would be less than the amount available for such purpose for the previous fiscal year, the amount that may be reserved under clause (i) shall be reduced such that the amount remaining

for the purpose of carrying out this section is not less than the amount available for such purpose for the previous fiscal year.

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

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

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

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

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

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

''(a) PURPOSE.—It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private

sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, in advance of, and immediately following a public health emergency, including threats posed by one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases.

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

''(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, result-

ing from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

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

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

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

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

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

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

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

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

''(3) update such guidelines as appropriate, including based on input received pursuant to subsections (c) and (e) and information resulting from applicable reports required under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (including any amendments made by such Act), to address new and emerging public health threats.

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

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

''(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care facilities (including hospitals, primary care clinics, community health centers, mental health facilities,

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

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

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

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

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

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

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

(b) GAO REPORT TO CONGRESS.—

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

which hospitals and health care facilities have implemented the recommended guidelines under section 319C–3(b) of the Public Health Service Act (as added by subsection (a)), including an analysis and evaluation of any challenges hospitals or health care facilities experienced in implementing such guidelines.

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

(A) data on the preparedness and response capabilities that have been informed by the guidelines under section 319C–3(b) of the Public Health Service Act to improve regional emergency health care preparedness and response capability, including hospital and health care facility capacity and medical surge capabilities to prepare for, and respond to, public health emergencies; and

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

pating in programs under section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) or in programs under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

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

(A) the Assistant Secretary for Preparedness and Response;

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

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

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

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

(F) the Secretary of Veterans Affairs.

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

this paragraph, a coalition shall include information on the progress that the coalition has made toward the implementation of section 319C–3 (or barriers to progress, if any).''.

(d) NATIONAL HEALTH SECURITY STRATEGY INCORPORATION OF REGIONALIZED EMERGENCY PREPAREDNESS AND RESPONSE.—Subparagraph (G) of section 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

''(a) MILITARY TRAUMA TEAM PLACEMENT PROGRAM.—

''(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Secretary of Defense, shall award grants to not more than 20 eligible high acuity trauma centers to enable military

trauma teams to provide, on a full-time basis, trauma care and related acute care at such trauma centers.

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

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

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

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

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

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

provide trauma care and related acute care at such trauma centers.

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

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

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

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

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

''(c) GRANT REQUIREMENTS.—

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

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

''(B) be deployed by the Secretary of Defense, in consultation with the Secretary of Health and Human Services, for response to a public health emergency pursuant to section 319.

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

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

''(e) REPORTING REQUIREMENTS.—

''(1) REPORT TO THE SECRETARY AND THE SECRETARY OF DEFENSE.—Each eligible trauma center or eligible high acuity trauma center awarded a grant under subsection (a) or (b) for a year shall

submit to the Secretary and the Secretary of Defense a report for such year that includes information on—

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

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

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

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

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

"(2) REPORT TO CONGRESS.—Not less than once every 2 years, the Secretary, in consultation with the Secretary of Defense, shall submit a report to the congressional committees of jurisdiction that includes information on the effect of placing military

trauma care providers in trauma centers awarded grants under this section on—

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

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

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

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

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

"(F) the capability of military trauma care providers to participate as part of a medical response during or in advance of a public health emergency, as determined by the Secretary, or a mass casualty incident.

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

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

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

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

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

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

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

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

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

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

''(i) affiliated with a medical school;

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

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

''(E) Such trauma center serves as a medical and public health preparedness and response leader for its community, such as by participating in a partnership for State and re-

gional hospital preparedness established under section 319C–2 or 319C–3.

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

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

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

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $11,500,000 for each of fiscal years 2019 through 2023.''.

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

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

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

(2) in subsection (a)—

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

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

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

(D) by adding at the end the following:

''(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years

2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.'';

(3) in subsection (b)—

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

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

(C) in paragraph (2)—

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

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

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

''(3) STANDARDS.—

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

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

(4) in subsection (c)—

(A) in paragraph (1)—

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

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

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

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

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

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

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

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

(C) in paragraph (3)—

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

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

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

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

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

''(A) IN GENERAL.—The network''; and

(iv) by adding at the end the following:

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

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

(D) in paragraph (5)—

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

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

''(A) IN GENERAL.—In establishing'';

(iii) by adding at the end the following:

''(B) PUBLIC MEETING.—

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

functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

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

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

''(I) data elements, including minimal or essential data elements,

that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

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

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

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

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

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

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

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

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

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

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

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

(IV) by adding at the end the following:

''(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, tribal, and territorial public health entities may

utilize, on a voluntary basis, as a part of the network.'';

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

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

''(6) STRATEGY AND IMPLEMENTATION PLAN.—

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

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

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

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

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

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

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

"(IV) test and evaluate capabilities of the interoperable network of

systems to improve situational awareness and biosurveillance capabilities;

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

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

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

''(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situa-

tional awareness and biosurveillance network under paragraph (1);

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

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

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

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

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

(ii) in subparagraph (B)—

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

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

(iii) in subparagraph (C)—

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

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

(iv) by adding at the end the following:

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

(H) by adding at the end the following:

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

and capabilities of the nationwide public health situational awareness and biosurveillance network.'';

(5) in subsection (d)—

(A) in paragraph (1)—

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

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

(B) in paragraph (2)—

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

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

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

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

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

''(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, tribes, and territories or a consortium of States, lo-

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

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

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

''(f) PERSONNEL AUTHORITIES.—

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

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

''(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in

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

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

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

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

plicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.''.

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

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

(1) an identification of technological, operational, and programmatic successes and failures of domestic detection programs supported by Federal departments and agencies for intentionally-intro-

duced or accidentally-released biological threat agents and naturally occurring infectious diseases;

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

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

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

(B) recover live biological agents from collection devices;

(C) determine the geographical distribution of biological agents;

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

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

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

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

(A) biological threat detection requirements or standards;

(B) a standardized integration strategy;

(C) training requirements or guidelines;

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

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

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

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

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

(1) in subsection (b)—

(A) in paragraph (1)—

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

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

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

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

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

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

torial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);

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

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

''(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such public

health emergency or potential public health emergency, including the systems under section 319D;

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

''(F) carry out other activities, as the Secretary determines applicable and appropriate.''; and

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

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

atives on policies to improve such Fund for the uses described in paragraph (2).

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

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

''(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.''; and

(2) in subsection (c)—

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

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

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

(a) IN GENERAL.—Section 319I (42 U.S.C. 247d–7b) is amended—

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

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

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

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

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

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

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

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

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

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

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

"SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DURING A PUBLIC HEALTH EMERGENCY.

"(a) LIMITATION ON LIABILITY.—Notwithstanding any other provision of law, a health care professional who is a member of the Medical Reserve Corps under section 2813 or who is included in the Emergency System for Advance Registration of Volunteer Health Professionals under section 319I and who—

"(1) is responding—

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

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

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

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

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

''(C) in the health care professional's capacity as a member of the Medical Reserve Corps or a professional included in the Emergency System for Advance Registration of Volunteer Health Professionals under section 319I; and

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

''(3) prior to the rendering of such act or omission, was authorized by the State's authorization of deploying such State's Emergency System for Advance Registration of Volunteer Health Professionals

described in section 319I or the Medical Reserve Corps established under section 2813, to provide health care services,

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

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

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

''(d) DEFINITIONS.—In this section:

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

''(2) The term 'health care services' means any services provided by a health care professional, or by

any individual working under the supervision of a health care professional, that relate to—

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

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

"(e) EFFECTIVE DATE.—

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

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

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

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

(2) the number of health care providers who are credentialed to provide services during the period of a public health emergency declaration, including those who are credentialed though programs established in the Emergency System for Advance Registration of Volunteer Health Professionals under such section 319I and those credentialed by authorities within the State in which the emergency occurred;

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

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

SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUPPLY.

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

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

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

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

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

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

(a) STUDY.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an agreement with an appropriate entity to conduct a study regarding the public health preparedness and response capabilities and medical surge capacities of hospitals, long-term care facilities, and other health care facilities to prepare for, and respond to, public health emergencies, including natural disasters.

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

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

(A) an evaluation of the current benchmarks and objective standards, as applicable, related to programs that support hospitals, long-term care facilities, and other health care facilities, and their effect on improving public health preparedness and response capabilities and medical surge capacities, including the

Hospital Preparedness Program, the Public Health Emergency Preparedness cooperative agreements, and the Regional Health Care Emergency Preparedness and Response Systems under section 319C–3 of the Public Health Service Act (as added by section 203);

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

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

(D) an evaluation of coordination efforts between the recipients of Federal funding for programs described in subparagraph (A) and

environmental health agencies with expertise in emergency preparedness and response planning for hospitals, long-term care facilities, and other health care facilities; and

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

(b) REPORT.—

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

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

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

(B) provide recommendations for improving public health preparedness and response ca-

pability and medical surge capacity for hospitals, long-term care facilities, and other health care facilities, including—

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

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

TITLE III—REACHING ALL COMMUNITIES

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

(a) NATIONAL DISASTER MEDICAL SYSTEM.—

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

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

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

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

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

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

''(ii) an assessment of the available workforce of the intermittent disaster re-

sponse personnel described in subsection (c);

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

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

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

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

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

''(3) NOTIFICATION.—Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster-response personnel

of the National Disaster Medical System is insufficient to address a public health emergency or potential public health emergency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing—

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

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

"(4) CERTAIN APPOINTMENTS.—

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

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

(4) AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) (42 U.S.C. 300hh–11(g)) is amended by striking ''$52,700,000 for each of fiscal years 2014 through 2018'' and inserting ''$57,400,000 for each of fiscal years 2019 through 2023''.

(b) VOLUNTEER MEDICAL RESERVE CORPS.—

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

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

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

(1) in subsection (a)—

(A) in paragraph (1)—

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

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

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

(2) in subsection (c)—

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

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

(B) by adding at the end the following:

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

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

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

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

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

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

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

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

''(E) an individual appointed to the National Disaster Medical System under section

2812 of the Public Health Service Act (42 U.S.C. 300hh–11) who is performing official duties of the Department of Health and Human Services, if those official duties are—

''(i) related to responding to a public health emergency or potential public health emergency, or other activities for which the Secretary of Health and Human Services has activated such National Disaster Medical System; and

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

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

(e) MISSION READINESS REPORT TO CONGRESS.—

(1) REPORT.—Not later than one year after the date of enactment of this section, the Comptroller General of the United States (referred to in this subsection as the ''Comptroller General'') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the medical surge capacity of the

United States in the event of a public health emergency, including the capacity and capability of the current health care workforce to prepare for, and respond to the full range of public health emergencies or potential public health emergencies, and recommendations to address any gaps identified in such workforce.

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

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

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

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

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

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

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

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

(a) COORDINATION OF PREPAREDNESS.—Section 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by adding at the end the following: ''Such logistical support shall include working with other relevant Federal, State,

local, tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency determined by the Secretary pursuant to section 319(a) or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.''.

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

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

(1) RAPID DELIVERY STUDY.—The Assistant Secretary for Preparedness and Response may con-

duct a study on issues that have the potential to adversely affect the handling and rapid delivery of medical countermeasures to individuals during public health emergencies occurring in the United States.

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

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

SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.

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

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

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

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

(1) by striking ''elderly'' and inserting ''older adults''; and

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

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

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

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

(3) by adding at the end the following:

''(9) facilitate coordination to ensure that, in implementing the situational awareness and biosurveillance network under section 319D, the Sec-

retary considers incorporating data and information from Federal, State, local, tribal, and territorial public health officials and entities relevant to detecting emerging public health threats that may affect at-risk individuals, such as pregnant and postpartum women and infants, including adverse health outcomes of such populations related to such emerging public health threats.''.

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

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

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

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

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

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

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

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

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

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

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

''(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies, including pursuant to section 319C–3; and

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

SEC. 305. NATIONAL ADVISORY COMMITTEES ON DISASTERS.

(a) REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.—Section 2811A (42 U.S.C. 300hh–10a) is amended—

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

(2) in subsection (d)—

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

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

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

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

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

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

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

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

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

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

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

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

''(3) FEDERAL MEMBERS.—The Advisory Committee under paragraph (1) shall include the following Federal members or their designees (who may be non-voting members, as determined by the Secretary):

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

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

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

"(D) The Commissioner of Food and Drugs.

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

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

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

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

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

"(J) The Secretary of Education.

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

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

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

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

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

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

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

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

(b) AUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.—Subtitle B of title XXVIII (42 U.S.C. 300hh et seq.) is amended by inserting after section 2811A the following:

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

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

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

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

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

''(3) provide advice and consultation with respect to State emergency preparedness and response activities relating to seniors, including related drills

and exercises pursuant to the preparedness goals under section 2802(b).

''(c) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to the Secretary with respect to seniors and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this title and title III.

''(d) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 17 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

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

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

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

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

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

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

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

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

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

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

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

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

''(L) Representatives of such other Federal agencies (such as the Department of Energy and the Department of Homeland Security) as

the Secretary determines necessary to fulfill the duties of the Advisory Committee.

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

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

''(g) SUNSET.—

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

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

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

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

''(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security, shall establish a national advisory committee to be known as the Na-

tional Advisory Committee on Individuals with Disabilities and Disasters (referred to in this section as the 'Advisory Committee').

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

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

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

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

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary, in consultation with such other heads of agencies and departments as appropriate, shall appoint not more than 17 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(g) SUNSET.—

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

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

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

''SEC. 2811D. ADVISORY COMMITTEE COORDINATION.

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

meetings under any of sections 2811A(e), 2811B(e), or 2811C(d).

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

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

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

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance regarding the ability of personnel funded by programs authorized under this Act (including the amendments made by this Act) to participate in drills and operational exercises related to all-hazards medical and public health preparedness and response. Such drills and operational exercises may include activities that incorporate medical surge capacity planning, medical

countermeasure distribution and administration, and preparing for and responding to identified threats for that region. Such personnel may include State, local, tribal, and territorial public health department or agency personnel funded under this Act (including the amendments made by this Act). The Secretary shall consult with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies as necessary and appropriate in the development of such guidance. The Secretary shall make the guidance available on the internet website of the Department of Health and Human Services.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

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

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

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

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

SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

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

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

''(a) IN GENERAL.—The Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the 'PHEMCE').

The Assistant Secretary for Preparedness and Response shall serve as chair of the PHEMCE.

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

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

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

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

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

''(5) The Secretary of Defense.

''(6) The Secretary of Homeland Security.

''(7) The Secretary of Agriculture.

''(8) The Secretary of Veterans Affairs.

''(9) The Director of National Intelligence.

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

''(c) FUNCTIONS.—

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

''(A) Utilize a process to make recommendations to the Secretary regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization with respect to countermeasures, as defined in section 319F–2(c), including prioritization based on the health security needs of the United States. Such recommendations shall be informed by, when available and practicable, the National Health Security Strategy pursuant to section 2802, the Strategic National Stockpile needs pursuant to section 319F–2, and assessments of current national security threats, including chemical, biological, radiological, and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

''(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures

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

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

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

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

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

(1) in paragraph (1)—

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

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

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

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

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

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

(2) in paragraph (1)—

(A) by inserting ''the Assistant Secretary for Preparedness and Response and'' after ''collaboration with'';

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

(C) by inserting ''and, as informed by existing recommendations of, or consultations

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

(D) by striking the second sentence;

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

''(2) THREAT-BASED REVIEW.—

''(A) IN GENERAL.—The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review shall be submitted on June 15, 2019, and on March 15 of each year thereafter, to the Committee on Health, Education, Labor, and Pen-

sions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, in a manner that does not compromise national security.

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

''(i) information regarding—

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

''(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such

products and ancillary medical supplies in the health care system;

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

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

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

''(VI) whether such countermeasure is replenishing an expiring or expired countermeasure, is a different countermeasure with the same indica-

tion that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

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

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

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

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

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

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

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

''(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary

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

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

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

(F) by adding at the end the following:

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

''(J) provide assistance, including technical assistance, to maintain and improve State and local public health preparedness capabilities to

distribute and dispense medical countermeasures and products from the stockpile, as appropriate.''; and

(5) by adding at the end the following:

''(5) GAO REPORT.—

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

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

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

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

''(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development fund-

ing from the Biomedical Advanced Research and Development Authority;

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

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

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

''(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such

change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities; and

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

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

troller General shall submit an unclassified version of the review to the congressional committees of jurisdiction.''.

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

(c) AUTHORIZATION OF APPROPRIATIONS, STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42

U.S.C. 247d–6b(f)(1)) is amended by striking ''$533,800,000 for each of fiscal years 2014 through 2018'' and inserting ''$610,000,000 for each of fiscal years 2019 through 2023, to remain available until expended''.

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

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

''(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat

(including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, countermeasures and products, as applicable, to address areas including—

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

''(ii) threats that consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including

multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material); and

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

(b) PROTECTION OF NATIONAL SECURITY FROM THREATS.—Section 2811 (42 U.S.C. 300hh–10) is amended by adding at the end the following:

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

''(1) IN GENERAL.—In carrying out subsection (b)(3), the Assistant Secretary for Preparedness and Response shall implement strategic initiatives or activities to address threats, including pandemic influenza and which may include a chemical, biological, radiological, or nuclear agent (including any such

agent with a significant potential to become a pandemic), that pose a significant level of risk to public health and national security based on the characteristics of such threat. Such initiatives shall include activities to—

''(A) accelerate and support the advanced research, development, manufacturing capacity, procurement, and stockpiling of countermeasures, including initiatives under section 319L(c)(4)(F);

''(B) support the development and manufacturing of virus seeds, clinical trial lots, and stockpiles of novel virus strains; and

''(C) maintain or improve preparedness activities, including for pandemic influenza.

''(2) AUTHORIZATION OF APPROPRIATIONS.—

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

''(B) SUPPLEMENT, NOT SUPPLANT.—Amounts appropriated under this paragraph shall be used to supplement and not supplant funds provided under sections 319L(d) and 319F–2(g).

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

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

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

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

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

(2) by adding at the end the following:

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

''(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pan-

demic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

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

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

SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.

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

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

(2) in subparagraph (A)—

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

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

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

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

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

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

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

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

SEC. 502. MATERIAL THREAT AND MEDICAL COUNTERMEASURE NOTIFICATIONS.

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

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

SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT PLANS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) by striking ''$2,800,000,000 for the period of fiscal years 2014 through 2018'' and inserting ''$7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended''; and

(2) by striking the second sentence.

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

SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTIBIOTIC RESISTANCE.

(a) ADVISORY COUNCIL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may continue the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, referred to in this section as the ''Advisory Council''.

(b) DUTIES.—The Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving—

(1) the effectiveness of antibiotics;

(2) research and advanced research on, and the development of, improved and innovative methods

for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities;

(3) surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics;

(4) education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals;

(5) methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections, including stewardship programs; and

(6) coordination with respect to international efforts in order to inform and advance United States capabilities to combat antibiotic resistance.

(c) MEETINGS AND COORDINATION.—

(1) MEETINGS.—The Advisory Council shall meet not less than biannually and, to the extent practicable, in coordination with meetings of the Antimicrobial Resistance Task Force established in section 319E(a) of the Public Health Service Act.

(2) COORDINATION.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the Antimicrobial Resistance Task Force established under section 319E(a) of the Public Health Service Act (42 U.S.C. 247d–5(a)).

(d) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the activities and duties of the Advisory Council.

(e) EXTENSION OF ADVISORY COUNCIL.—Not later than October 1, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a recommendation on whether the Advisory Council should be extended, and in addition, identify whether there are other committees, councils, or task forces that have overlapping or similar duties to that of the Advisory Council, and whether such committees, councils, or task forces should be combined, including with respect to section 319E(a) of the Public Health Service Act (42 U.S.C. 247d–5(a)).

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

SEC. 601. ADMINISTRATION OF COUNTERMEASURES.

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

SEC. 602. UPDATING DEFINITIONS OF OTHER TRANSACTIONS.

Section 319L (42 U.S.C. 247d–7e) is amended—

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

(2) in subsection (c)(5)(A)—

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

(B) in clause (ii)—

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

''(I) IN GENERAL.—To the maximum extent practicable, competitive

procedures shall be used when entering into transactions to carry out projects under this subsection.''; and

(ii) in subclause (II)—

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

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

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

SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—The purpose of this section (including section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b)) is to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encour-

aging submission of data and information to support the development of such products, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), including data and information submitted to medical countermeasure master files or other master files.

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

''SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

''(a) APPLICABILITY OF REFERENCE.—

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

with applicable privacy and confidentiality protocols and regulations.

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

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

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

''(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified counter-

measures, or qualified pandemic or epidemic products; and

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

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

''(c) SPONSOR REFERENCE.—

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

''(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the

Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

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

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

''(1) IN GENERAL.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure mas-

ter file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

''(2) CERTAIN APPLICATIONS.—If the Secretary has reviewed and relied upon specified data or information within a medical countermeasure master file to support the conditional approval of an application under section 571 to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how such data or information contained in such application meets the standards of evidence under subsection (c) or (d) of section 505, subsection (d) of section 512, or section 351 of the Public Health Service Act (as applicable), which shall not include any trade secret or confidential commercial information.

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

''(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this Act or section 351 of the Public Health Service Act (as such applicable Act is in effect on the day before the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act;

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

''(3) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 505(i),

505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

''(f) DEFINITIONS.—In this section:

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

''(2) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biological product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of

a new animal drug under section 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or a request for an emergency use authorization under section 564 to support—

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

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

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

(c) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary

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

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

manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

SEC. 604. ANIMAL RULE REPORT.

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

(1) The extent to which advanced development and review of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug Administration, including activities that facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal rule, consistent with the recommendations in

the animal rule guidance, issued pursuant to section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled ''Product Development Under the Animal Rule: Guidance for Industry'' (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.

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

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

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

has assisted in achieving the purposes described in paragraphs (1), (2), and (3).

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

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

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

(3) other biodefense stakeholders, as applicable.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a) and recommendations to improve the application and consistency of the re-

quirements under subsections (c) and (d) of section 565 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

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

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

(a) MEETING.—

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

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

(A) shall include—

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

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

(B) may include—

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

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

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

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

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

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

(B) national security implications, including—

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

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

(iii) security measures to monitor and assess the potential threat that may result

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

(b) REPORT.—Not later than 270 days after the meeting described in subsection (a) is held, the Assistant Secretary for Preparedness and Response shall issue a report to the congressional committees of jurisdiction on the topics discussed at such meeting, and provide recommendations, as applicable, to utilize innovations in genomic engineering (including genome editing) and related technologies as a part of preparedness and response activities to advance national health security. Such report shall be issued in a manner that does not compromise national security.

SEC. 606. REPORT ON VACCINES DEVELOPMENT.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing efforts and activities to coordinate with other countries and international partners during recent public health emergencies with respect to the research and advanced research on, and development

of, qualified pandemic or epidemic products (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)). Such report may include information regarding relevant work carried out under section 319L(c)(5)(E) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)(E)), through public-private partnerships, and through collaborations with other countries to assist with or expedite the research and development of qualified pandemic or epidemic products. Such report shall not include information that may compromise national security.

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

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

(1) in subsection (a)(1)(B)—

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

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

(2) in subsection (b)—

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

(B) in paragraph (2)—

(i) in subparagraph (A)—

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

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

(III) by adding at the end the following:

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

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

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

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

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

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

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

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

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

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

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

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

(3) in subsection (f)—

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

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

(C) in paragraph (3)—

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

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

(b) EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.—Section 2821 (42 U.S.C. 300hh–31) is amended—

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

(2) in subsection (b), by striking "2010 through 2013" and inserting "2019 through 2023".

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

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

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

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

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

(e) LIMITED ANTITRUST EXEMPTION.—

(1) IN GENERAL.—Section 405 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417; 42 U.S.C. 247d–6a note) is amended—

(A) in subsection (a)(1)(A)—

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

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

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

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

(B) in subsection (b), by striking ''12-year'' and inserting ''17-year'';

(C) by redesignating such section 405 as section 319L–1; and

(D) by transferring such section 319L–1, as redesignated, to the Public Health Service Act (42 U.S.C. 201 et seq.), to appear after section 319L of such Act (42 U.S.C. 247d–7e).

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

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

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

"(A) NON-DISCLOSURE OF INFORMATION.—

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

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

"(I) specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and

development carried out under subsection (c);

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

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

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

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

''(C) REPORTING.—One year after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, and annually thereafter, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the number of instances in which the Secretary has

used the authority under this subsection to withhold information from disclosure, as well as the nature of any request under section 552 of title 5, United States Code that was denied using such authority.''; and

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

SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.

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

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

SEC. 703. CYBERSECURITY.

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

(1) STRATEGY.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall prepare and submit to the relevant committees of Congress a

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

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

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

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

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

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

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

SEC. 704. STRATEGY AND REPORT.

Not later than 14 days after the date of the enactment of this Act, the Secretary of Health and Human Services, in coordination with the Assistant Secretary for Preparedness and Response and the Assistant Secretary for the Administration on Children and Families or other appropriate office, and in collaboration with other departments, as appropriate, shall submit to the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and other relevant congressional committees—

(1) a formal strategy, including interdepartmental actions and efforts to reunify children with their parents or guardians, in all cases in which such children have been separated from their parents or guardians as a result of the initiative announced on April 6, 2018, and due to prosecution under section 275(a) of the Immigration and Nationality Act (8 U.S.C. 1325(a)), if the parent or guardian chooses such reunification and the child—

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

(B) as of the date of the enactment of this Act, remains in the care of the Department of Health and Human Services; and

(C) can be safely reunited with such parent or guardian; and

(2) a report on challenges and deficiencies related to the oversight of, and care for, unaccompanied alien children and appropriately reuniting such children with their parents or guardians, and the actions taken to address any challenges and deficiencies related to unaccompanied alien children in the custody of the Department of Health and Human Services, including deficiencies identified and publicly reported by Congress, the Government Accountability Office, or the Inspectors General of the Department of Health and Human Services or other Federal departments.

SEC. 705. TECHNICAL AMENDMENTS.

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

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

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

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

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

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

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

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

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

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

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

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

''(A) IN GENERAL.—Nothing in'';

(2) by inserting ''or directing'' after ''authorizing'';

(3) by striking ''disclose any'' and inserting ''disclose—

''(i) any'';

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

(5) by adding at the end the following:

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

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

DIVISION B—OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM

SECTION 1000. SHORT TITLE; REFERENCES IN DIVISION.

(a) SHORT TITLE.—This division may be cited as the ''Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018''.

(b) REFERENCES.—Except as otherwise specified, any reference to ''this Act'' contained in this division shall be treated as referring only to the provisions of this division.

TITLE I—OTC DRUG REVIEW

SEC. 1001. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355g) the following:

"SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

"(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs marketed without an approved drug application under section 505, as of the date of the enactment of this section, shall be treated in accordance with this subsection.

"(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective under section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

"(A) the drug is—

"(i) in conformity with the requirements for nonprescription use of a final

monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

''(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2); or

''(B) the drug is—

''(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any appli-

cable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

"(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

"(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in

section 201.327 of title 21, Code of Federal Regulations.

''(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

''(A) the drug is—

''(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with—

''(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

"(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

"(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (b) or (k); and

"(iii) in a dosage form that, immediately prior to the date of the enactment of this section, had been used to a material extent and for a material time under section 201(p)(2); or

"(B) the drug is—

"(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

"(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

"(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

"(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505 beginning on the day that is 180 calendar days after

the date of the enactment of this section, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

''(5) DRUGS NOT GRASE DEEMED NEW DRUGS.—A drug that the Secretary has determined not to be generally recognized as safe and effective under section 201(p)(1) under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505.

''(6) OTHER DRUGS DEEMED NEW DRUGS.—Except as provided in subsection (m), a drug is deemed to be a new drug under section 201(p) and misbranded under section 502(ee) if the drug—

''(A) is not subject to section 503(b)(1); and

''(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (b)(1)(B).

''(b) ADMINISTRATIVE ORDERS.—

''(1) IN GENERAL.—

''(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be—

''(i) not subject to section 503(b)(1); and

''(ii) generally recognized as safe and effective under section 201(p)(1).

''(B) EFFECT.—A drug or combination of drugs shall be deemed to not require approval under section 505 if such drug or combination of drugs—

''(i) is determined by the Secretary to meet the conditions specified in clauses (i) and (ii) of subparagraph (A);

''(ii) is marketed in conformity with an administrative order under this subsection;

''(iii) meets the general requirements for nonprescription drugs; and

''(iv) meets the requirements under subsections (c) and (k).

''(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective under section 201(p)(1) if—

''(i) the evidence shows that the drug is not generally recognized as safe and effective under section 201(p)(1); or

''(ii) the evidence is inadequate to show that the drug is generally recognized as safe and effective under section 201(p)(1).

''(2) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) upon the Secretary's initiative, the Secretary shall—

''(i) make reasonable efforts to notify informally, not later than 2 business days before the issuance of the proposed order, the sponsors of drugs who have a listing in effect under section 510(j) for the drugs or combination of drugs that will be subject to the administrative order;

''(ii) after any such reasonable efforts of notification—

''(I) issue a proposed administrative order by publishing it on the website of the Food and Drug Administration and include in such order the reasons for the issuance of such order; and

''(II) publish a notice of availability of such proposed order in the Federal Register;

''(iii) except as provided in subparagraph (B), provide for a public comment period with respect to such proposed order of not less than 45 calendar days; and

''(iv) if, after completion of the proceedings specified in clauses (i) through (iii), the Secretary determines that it is appropriate to issue a final administrative order—

''(I) issue the final administrative order, together with a detailed statement of reasons, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

"(II) publish a notice of such final administrative order in the Federal Register;

"(III) afford requestors of drugs that will be subject to such order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially must be requested within 45 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30 calendar days of the prior decision; and

"(IV) except with respect to drugs described in paragraph (3)(B), upon completion of the formal dispute resolution procedure, inform the persons which sought such dispute resolution of their right to request a hearing.

"(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (a)(3) is not

generally recognized as safe and effective under section 201(p)(1), the Secretary shall follow the procedures in subparagraph (A), except that—

''(i) the proposed order shall include notice of—

''(I) the general categories of data the Secretary has determined necessary to establish that the drug is generally recognized as safe and effective under section 201(p)(1); and

''(II) the format for submissions by interested persons;

''(ii) the Secretary shall provide for a public comment period of no less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

''(iii) any person who submits data in such comment period shall include a certification that the person has submitted all evidence created, obtained, or received by that person that is both within the categories of data identified in the proposed order and relevant to a determination as to

whether the drug is generally recognized as safe and effective under section 201(p)(1).

''(3) HEARINGS; JUDICIAL REVIEW.—

''(A) IN GENERAL.—Only a person who participated in each stage of formal dispute resolution under subclause (III) of paragraph (2)(A)(iv) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under such paragraph with respect to such drug. If a hearing is sought, such person must submit a request for a hearing, which shall be based solely on information in the administrative record, to the Secretary not later than 30 calendar days after receiving notice of the final decision of the formal dispute resolution procedure.

''(B) NO HEARING REQUIRED WITH RESPECT TO ORDERS RELATING TO CERTAIN DRUGS.—

''(i) IN GENERAL.—The Secretary shall not be required to provide notice and an opportunity for a hearing pursuant to paragraph (2)(A)(iv) if the final administrative order involved relates to a drug—

"(I) that is described in subsection (a)(3)(A); and

"(II) with respect to which no human or non-human data studies relevant to the safety or effectiveness of such drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to such drug.

"(ii) HUMAN DATA STUDIES AND NON-HUMAN DATA DEFINED.—In this subparagraph:

"(I) The term 'human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

"(II) The term 'non-human data' means data from testing other than with human subjects which provides information concerning safety or effectiveness.

"(C) HEARING PROCEDURES.—

"(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv), does not identify the existence of a genuine and substantial question of material fact, the Secretary may deny such request. In making such a determination, the Secretary may consider only information and data that are based on relevant and reliable scientific principles and methodologies.

"(ii) SINGLE HEARING FOR MULTIPLE RELATED REQUESTS.—If more than one request for a hearing is submitted with respect to the same administrative order under subparagraph (A), the Secretary may direct that a single hearing be conducted in which all persons whose hearing requests were granted may participate.

"(iii) PRESIDING OFFICER.—The presiding officer of a hearing requested under subparagraph (A) shall—

''(I) be designated by the Secretary;

''(II) not be an employee of the Center for Drug Evaluation and Research; and

''(III) not have been previously involved in the development of the administrative order involved or proceedings relating to that administrative order.

''(iv) RIGHTS OF PARTIES TO HEARING.—The parties to a hearing requested under subparagraph (A) shall have the right to present testimony, including testimony of expert witnesses, and to cross-examine witnesses presented by other parties. Where appropriate, the presiding officer may require that cross-examination by parties representing substantially the same interests be consolidated to promote efficiency and avoid duplication.

''(v) FINAL DECISION.—

''(I) At the conclusion of a hearing requested under subparagraph (A), the presiding officer of the hear-

ing shall issue a decision containing findings of fact and conclusions of law. The decision of the presiding officer shall be final.

''(II) The final decision may not take effect until the period under subparagraph (D)(ii) for submitting a request for judicial review of such decision expires.

''(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—

''(i) IN GENERAL.—The procedures described in section 505(h) shall apply with respect to judicial review of final administrative orders issued under this subsection in the same manner and to the same extent as such section applies to an order described in such section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in such section.

''(ii) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph

and seeking judicial review of a final administrative order issued under this subsection shall file such request for judicial review not later than 60 calendar days after the latest of—

"(I) the date on which notice of such order is published;

"(II) the date on which a hearing with respect to such order is denied under subparagraph (B) or (C)(i);

"(III) the date on which a final decision is made following a hearing under subparagraph (C)(v); or

"(IV) if no hearing is requested, the date on which the time for requesting a hearing expires.

"(4) EXPEDITED PROCEDURE WITH RESPECT TO ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

"(A) IMMINENT HAZARD TO THE PUBLIC HEALTH.—

"(i) IN GENERAL.—In the case of a determination by the Secretary that a drug, class of drugs, or combination of drugs subject to this section poses an im-

minent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of such order under this subparagraph, sponsors who have a listing in effect under section 510(j) for such drug or combination of drugs—

"(I) may issue an interim final administrative order for such drug, class of drugs, or combination of drugs under paragraph (1), together with a detailed statement of the reasons for such order;

"(II) shall publish in the Federal Register a notice of availability of any such order; and

"(III) shall provide for a public comment period of at least 45 calendar days with respect to such interim final order.

"(ii) NONDELEGATION.—The Secretary may not delegate the authority to issue an interim final administrative order under this subparagraph.

"(B) SAFETY LABELING CHANGES.—

"(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

"(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect under section 510(j) for such drug or combination of drugs;

"(II) after reasonable efforts of notification, issue an interim final administrative order in accordance with paragraph (1) to require such change, together with a detailed statement of the reasons for such order;

"(III) publish in the Federal Register a notice of availability of such order; and

"(IV) provide for a public comment period of at least 45 calendar days with respect to such interim final order.

"(ii) CONTENT OF ORDER.—An interim final order issued under this subparagraph with respect to the labeling of a drug may provide for new warnings and other information required for safe use of the drug.

"(C) EFFECTIVE DATE.—An order under subparagraph (A) or (B) shall take effect on a date specified by the Secretary.

"(D) FINAL ORDER.—After the completion of the proceedings in subparagraph (A) or (B), the Secretary shall—

"(i) issue a final order in accordance with paragraph (1);

"(ii) publish a notice of availability of such final administrative order in the Federal Register; and

"(iii) afford sponsors of such drugs that will be subject to such an order the opportunity for formal dispute resolution up to the level of the Director of the Cen-

ter for Drug Evaluation and Research, which must initially be within 45 calendar days of the issuance of the order, and for subsequent levels of appeal, within 30 calendar days of the prior decision.

''(E) HEARINGS.—A sponsor of a drug subject to a final order issued under subparagraph (D) and that participated in each stage of formal dispute resolution under clause (iii) of such subparagraph may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), shall apply with respect to a hearing on such order in the same manner and to the same extent as such provisions apply with respect to a hearing on an administrative order issued under paragraph (2)(A)(iv).

''(F) TIMING.—

''(i) FINAL ORDER AND HEARING.—The Secretary shall—

''(I) not later than 6 months after the date on which the comment period closes under subparagraph (A)

or (B), issue a final order in accordance with paragraph (1); and

''(II) not later than 12 months after the date on which such final order is issued, complete any hearing under subparagraph (E).

''(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

''(G) JUDICIAL REVIEW.—A final order issued pursuant to subparagraph (F) shall be subject to judicial review in accordance with paragraph (3)(D).

''(5) ADMINISTRATIVE ORDER INITIATED AT THE REQUEST OF A REQUESTOR.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs—

''(i) the Secretary shall, after receiving a request under this subparagraph, determine whether the request is sufficiently complete and formatted to permit a substantive review;

''(ii) if the Secretary determines that the request is sufficiently complete and formatted to permit a substantive review, the Secretary shall—

''(I) file the request; and

''(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3); and

''(iii) except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed over protest, and the Secretary shall initiate proceedings to review the request in accordance with paragraph (2)(A).

''(B) REQUEST TO INITIATE PROCEEDINGS.—

"(i) IN GENERAL.—A requestor seeking an administrative order under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

"(I) determining whether a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505; or

"(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505,

if, absent such a changed condition of use, such drug is—

"(aa) generally recognized as safe and effective under section 201(p)(1) in accordance with subsection (a)(1), (a)(2), or an order under this subsection; or

"(bb) subject to subsection (a)(3), but only if such requestor initiates such request in conjunction with a request for the Secretary to determine whether such drug is generally recognized as safe and effective under section 201(p)(1), which is filed by the Secretary under subparagraph (A)(ii).

"(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective under section 201(p)(1) under para-

graph (1) and issues a final order announcing that determination.

''(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (d)(2)(B). Notwithstanding any other provision of this section, if such request is withdrawn, the Secretary may cease proceedings under this subparagraph.

''(C) EXCLUSIVITY.—

''(i) IN GENERAL.—A final administrative order issued in response to a request under this section shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such order), for a period of 18 months following the effective date of such final order and beginning on the date the requestor may lawfully market such drugs pursuant to the order, to market drugs—

''(I) incorporating changes described in clause (ii); and

''(II) subject to the limitations under clause (iv).

''(ii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (i), which—

''(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a drug described in clause (iii); or

''(II) provides for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of such order.

''(iii) DRUGS DESCRIBED.—The drugs described in this clause are drugs—

''(I) specified in subsection (a)(1), (a)(2), or (a)(3);

''(II) subject to a final order issued under this section;

"(III) subject to a final sunscreen order (as defined in section 586(2)(A)); or

"(IV) described in subsection (m)(1), other than drugs subject to an active enforcement action under chapter III of this Act.

"(iv) LIMITATIONS ON EXCLUSIVITY.—

"(I) IN GENERAL.—Only one 18-month period under this subparagraph shall be granted, under each order described in clause (i), with respect to changes (to the drug subject to such order) which are either—

"(aa) changes described in clause (ii)(I), relating to active ingredients; or

"(bb) changes described in clause (ii)(II), relating to conditions of use.

"(II) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug which are—

"(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 744L);

"(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to assure safe use; or

"(cc) changes related to methods of testing safety or efficacy.

"(v) NEW HUMAN DATA STUDIES DEFINED.—In this subparagraph, the term 'new human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies, the results of which—

"(I) have not been relied on by the Secretary to support—

"(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized

as safe and effective under section 201(p)(1); or

"(bb) approval of a drug that was approved under section 505; and

"(II) do not duplicate the results of another study that was relied on by the Secretary to support—

"(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 201(p)(1); or

"(bb) approval of a drug that was approved under section 505.

"(6) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

"(A) IN GENERAL.—In response to a request under this section that a drug described in subparagraph (B) be generally recognized as safe and effective, the Secretary—

"(i) may file such request, if the request includes information specified under subparagraph (C) with respect to safe nonprescription marketing and use of such drug; or

"(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file such request and require that nonprescription marketing of the drug be pursuant to a new drug application as described in subparagraph (D).

"(B) DRUG DESCRIBED.—A drug described in this subparagraph is a nonprescription drug which contains an active ingredient not previously incorporated in a drug—

"(i) specified in subsection (a)(1), (a)(2), or (a)(3);

"(ii) subject to a final order under this section; or

"(iii) subject to a final sunscreen order (as defined in section 586(2)(A)).

"(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in

this subparagraph, with respect to a request described in subparagraph (A)(i), is—

''(i) information sufficient for a prima facie demonstration that the drug subject to such request has a verifiable history of being marketed and safely used by consumers in the United States as a nonprescription drug under comparable conditions of use;

''(ii) if the drug has not been previously marketed in the United States as a nonprescription drug, information sufficient for a prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 802(b)(1)(A) or designated by the Secretary in accordance with section 802(b)(1)(B)—

''(I) for such period as needed to provide reasonable assurances concerning the safe nonprescription use of the drug; and

''(II) during such time was subject to sufficient monitoring by a reg-

ulatory body considered acceptable by the Secretary for such monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

''(iii) if the Secretary determines that information described in clause (i) or (ii) is not needed to provide a prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for such purposes.

''(D) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in subparagraph (A)(ii), the drug subject to such request may be re-submitted for filing only if—

''(i) the drug is marketed as a nonprescription drug, under conditions of use comparable to the conditions specified in the request, for such period as the Secretary determines appropriate (not to exceed 5 consecutive years) pursuant to an application approved under section 505; and

"(ii) during such period, 1,000,000 retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

"(E) RULE OF APPLICATION.—Except in the case of a request involving a drug described in section 586(9), as in effect on January 1, 2017, if the Secretary refuses to file a request under this paragraph, the requestor may not file such request over protest under paragraph (5)(A)(iii).

"(7) PACKAGING.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling. Such requirements may include unit dose packaging, requirements for products intended for use by pediatric populations, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements. This paragraph does not authorize the Food and Drug Administration to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

''(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

''(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

''(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph or tentative final monograph is described in this subparagraph if it—

''(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (a); and

''(ii) represents the most recently promulgated version of such conditions, including as modified, in whole or in part, by any proposed or final rule.

''(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be con-

strued to include any technical amendments to such order as the Secretary determines necessary to ensure that such order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of this Act (and regulations thereunder) and any other orders issued under this section.

''(c) PROCEDURE FOR MINOR CHANGES.—

''(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (a) or the subject of an order issued under subsection (b) may be made by a requestor without the issuance of an order under subsection (b) if—

''(A) the requestor maintains such information as is necessary to demonstrate that the change—

''(i) will not affect the safety or effectiveness of the drug; and

''(ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and

''(B) the change is in conformity with the requirements of an applicable administrative

order issued by the Secretary under paragraph (3).

''(2) ADDITIONAL INFORMATION.—

''(A) ACCESS TO RECORDS.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 704(a)(4), within 15 business days of receiving such a request, or such longer period as the Secretary may provide.

''(B) INSUFFICIENT INFORMATION.—If the Secretary determines that the information contained in such records is not sufficient to demonstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the Secretary—

''(i) may so inform the sponsor of the drug in writing; and

''(ii) if the Secretary so informs the sponsor, shall provide the sponsor of the drug with a reasonable opportunity to provide additional information.

''(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the sponsor fails to provide such additional information within a time pre-

scribed by the Secretary, or if the Secretary determines that such additional information does not demonstrate that the change does not—

"(i) affect the safety or effectiveness of the drug; or

"(ii) materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product,

the drug as modified is a new drug under section 201(p) and shall be deemed to be misbranded under section 502(ee).

"(3) DETERMINING WHETHER A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

"(A) IN GENERAL.—The Secretary shall issue one or more administrative orders specifying requirements for determining whether a minor change made by a sponsor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

''(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

''(d) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

''(1) IN GENERAL.—Subject to paragraph (2), any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an order under this section (including any minor change under subsection (c)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, shall not be disclosed to the public unless the requestor consents to that disclosure.

''(2) PUBLIC AVAILABILITY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall—

''(i) make any information submitted by a requestor in support of a request

under subsection (b)(5)(A) available to the public not later than the date on which the proposed order is issued; and

''(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

''(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

''(i) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1);

''(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws such request, in accordance with withdrawal procedures established by the Secretary, before the Secretary issues the proposed order;

''(iii) the Secretary requests and obtains the information under subsection (c)

and such information is not submitted in relation to an order under subsection (b); or

"(iv) the information is of the type contained in raw datasets.

"(e) UPDATES TO DRUG LISTING INFORMATION.—A sponsor who makes a change to a drug subject to this section shall submit updated drug listing information for the drug in accordance with section 510(j) within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor who was the order requestor with respect to an order subject to subsection (b)(5)(C) (or a licensee, assignee, or successor in interest of such requestor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

"(f) APPROVALS UNDER SECTION 505.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of an application for a drug under sections 505(b)(1), 505(b)(2), and 505(j). A determination under this section that a drug is not subject to section 503(b)(1), is generally recognized as safe and effective under section 201(p)(1), and is not a new drug under section 201(p) shall constitute a finding that the drug is safe and effective that may be relied upon

for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

''(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

''(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

''(2) a listing of all orders proposed and under development under subsection (b)(2), including—

''(A) a brief description of each such order; and

''(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a 3-year period.

''(h) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information nec-

essary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

''(i) PARTICIPATION OF MULTIPLE SPONSORS OR REQUESTORS.—The Secretary shall establish procedures to facilitate efficient participation by multiple sponsors or requestors in proceedings under this section, including provision for joint meetings with multiple sponsors or requestors or with organizations nominated by sponsors or requestors to represent their interests in a proceeding.

''(j) ELECTRONIC FORMAT.—All submissions under this section shall be in electronic format.

''(k) EFFECT ON EXISTING REGULATIONS GOVERNING NONPRESCRIPTION DRUGS.—

''(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify such regulations by means

of rulemaking in accordance with section 553 of title 5, United States Code.

"(2) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

"(A) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section, shall be deemed to be a final order under subsection (b).

"(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

"(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

"(ii) otherwise subject to an order under this section.

"(3) WITHDRAWAL OF REGULATIONS.—The Secretary shall withdraw regulations establishing final monographs and the procedures governing the

over-the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the day before the date of the enactment of this section), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

''(l) GUIDANCE.—The Secretary shall issue guidance that specifies—

''(1) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

''(2) the format and content of data submissions to the Secretary under this section;

''(3) the format of electronic submissions to the Secretary under this section;

''(4) consolidated proceedings for appeal and the procedures for such proceedings where appropriate; and

''(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (c)(3).

''(m) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

''(A) that is marketed without an application approved under section 505 as of the date of the enactment of this section;

''(B) that is not subject to an order issued under this section; and

''(C) to which paragraphs (1), (2), (3), (4), or (5) of subsection (a) do not apply.

''(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

''(A) Notwithstanding subsection (a), a drug described in subparagraph (B) may only be lawfully marketed, without an application approved under section 505, pursuant to an order issued under this section.

''(B) A drug described in this subparagraph is a drug which, prior to the date of the enactment of this section, the Secretary deter-

mined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase 'OTC drug review' was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section).

"(3) PRESERVATION OF AUTHORITY.—

"(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any provision of this Act other than this section.

"(B) Nothing in subsection (a) shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective under section 201(p)(1), as the Secretary determines appropriate.

"(n) INVESTIGATIONAL NEW DRUGS.—A drug is not subject to this section if an exemption for investigational use under section 505(i) is in effect for such drug.

"(o) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.

''(p) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5, United States Code.

''(q) DEFINITIONS.—In this section:

''(1) The term 'nonprescription drug' refers to a drug not subject to the requirements of section 503(b)(1).

''(2) The term 'sponsor' refers to any person marketing, manufacturing, or processing a drug that—

''(A) is listed pursuant to section 510(j); and

''(B) is or will be subject to an administrative order under this section of the Food and Drug Administration.

''(3) The term 'requestor' refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.''.

(b) GAO STUDY.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Rep-

resentatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and section 586C of such Act (21 U.S.C. 360fff–3), including the impact of such exclusivity on consumer access. Such study shall include—

(1) an analysis of the impact of exclusivity under such section 505G for nonprescription drug products, including—

(A) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

(B) whether the exclusivity for such drug products was granted for—

(i) a new active ingredient (including any ester or salt of the active ingredient); or

(ii) changes in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor were essential;

(C) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

(D) an analysis of the implementation of the exclusivity provision in such section 505G, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

(iii) the impact of such provision on competition in the nonprescription drug market;

(iv) the impact of such provision on consumer access to nonprescription drug products;

(v) the impact of such provision on the prices of nonprescription drug products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been sufficient to encourage the development of nonprescription drug prod-

ucts that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 505G have been sufficient incentive to encourage innovation in the nonprescription drug market; and

(2) an analysis of the impact of exclusivity under such section 586C for sunscreen ingredients, including—

(A) the number of sunscreen ingredients that were granted exclusivity and the specific ingredient that was determined to be generally recognized as safe and effective;

(B) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the sunscreen ingredient;

(C) whether, and to what extent, the sunscreen ingredient granted exclusivity had previously been available outside of the United States;

(D) an analysis of the implementation of the exclusivity provision in such section 586C, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the sunscreen market;

(iii) the impact of such provision on competition in the sunscreen market;

(iv) the impact of such provision on consumer access to sunscreen products;

(v) the impact of such provision on the prices of sunscreen products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been utilized by sunscreen ingredient sponsors and whether such process has been sufficient to encourage the development of sunscreen ingredients that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 586C have been sufficient incentive to encourage innovation in the sunscreen market.

(c) CONFORMING AMENDMENT.—Section 751(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r(d)(1)) is amended—

(1) in the matter preceding subparagraph (A)—

(A) by striking ''final regulation promulgated'' and inserting ''final order under section 505G''; and

(B) by striking ''and not misbranded''; and

(2) in subparagraph (A), by striking ''regulation in effect'' and inserting ''regulation or order in effect''.

SEC. 1002. MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(ee) If it is a nonprescription drug that is subject to section 505G, is not the subject of an application approved under section 505, and does not comply with the requirements under section 505G.

''(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.''.

SEC. 1003. DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG REVIEW.

(a) IN GENERAL.—Nothing in this Act (or the amendments made by this Act) shall apply to any nonprescription drug (as defined in section 505G(q) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act) which was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 1004. TREATMENT OF SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.—

(1) APPLICABILITY OF SECTION 505G FOR PENDING SUBMISSIONS.—

(A) IN GENERAL.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that, as of the date of enactment of this Act, is subject to a proposed sunscreen order under section 586C of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 360fff–3) may elect, by means of giving written notification to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(B) ELECTION EXERCISED.—Upon receipt by the Secretary of Health and Human Services of a timely notification under subparagraph (A)—

(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act; and

(ii) such order is deemed to have been accepted for filing under subsection (b)(6)(A)(i) of such section 505G.

(C) ELECTION NOT EXERCISED.—If a notification under subparagraph (A) is not received by the Secretary of Health and Human Services

within 180 calendar days of the date of enactment of this Act, the review of the proposed sunscreen order described in subparagraph (A)—

(i) shall continue under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); and

(ii) shall not be eligible for review under section 505G, added by section 1001 of this Act.

(2) DEFINITIONS.—In this subsection, the terms ''sponsor'', ''nonprescription'', ''sunscreen active ingredient'', and ''proposed sunscreen order'' have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

(1) FINAL SUNSCREEN ORDERS.—Paragraph (3) of section 586C(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amended to read as follows:

''(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final order under section 505G.''.

(2) MEETINGS.—Paragraph (7) of section 586C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended—

(A) by striking ''A sponsor may request'' and inserting the following:

''(A) IN GENERAL.—A sponsor may request''; and

(B) by adding at the end the following:

''(B) CONFIDENTIAL MEETINGS.—A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters relating to data requirements to support a general recognition of safety and effectiveness involving confidential information and public information related to such proposed sunscreen order, as appropriate. The Secretary shall convene a confidential meeting with such sponsor in a reasonable time period. If a sponsor requests more than one confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines that such additional confidential meeting

is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets. This subparagraph does not authorize the disclosure of confidential commercial information or trade secrets subject to 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(3) EXCLUSIVITY.—Section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) is amended by adding at the end the following:

''(f) EXCLUSIVITY.—

''(1) IN GENERAL.—A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) for a period of 18 months, to market a sunscreen ingredient under this section incorporating changes

described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

''(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

''(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described in this paragraph are sunscreen ingredients—

''(A) marketed in accordance with a final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687); or

''(B) marketed in accordance with a final order issued under this section.

''(4) LIMITATIONS ON EXCLUSIVITY.—Only one 18-month period may be granted per ingredient under paragraph (1).

''(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary at the time when a drug subject to such request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under paragraph (1).''.

(4) SUNSET PROVISION.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) is amended by adding at the end the following:

''SEC. 586H. SUNSET.

''This subchapter shall cease to be effective at the end of fiscal year 2022.''.

(5) TREATMENT OF FINAL SUNSCREEN ORDER.—The Federal Food, Drug, and Cosmetic Act is amended by striking section 586E of such Act (21 U.S.C. 360fff–5).

(c) TREATMENT OF AUTHORITY REGARDING FINALIZATION OF SUNSCREEN MONOGRAPH.—

(1) IN GENERAL.—

(A) REVISION OF FINAL SUNSCREEN ORDER.—Not later than November 26, 2019, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall amend and revise the final administrative order concerning nonprescription sunscreen (referred to in this subsection as the ''sunscreen order'') for which the content, prior to the date of enactment of this Act, was represented by the final monograph for sunscreen drug products set forth in part 352 of title 21, Code of Federal Regulations (as in effect on May 21, 1999).

(B) ISSUANCE OF REVISED SUNSCREEN ORDER; EFFECTIVE DATE.—A revised sunscreen order described in subparagraph (A) shall be—

(i) issued in accordance with the procedures described in section 505G(c)(2) of the Federal Food, Drug, and Cosmetic Act;

(ii) issued in proposed form not later than May 28, 2019;

(iii) effective not later than November 26, 2020; and

(iv) issued by the Secretary at least 1 year prior to the effective date of the revised order.

(2) REPORTS.—If a revised sunscreen order issued under paragraph (1) does not include provisions related to the effectiveness of various sun protection factor levels, and does not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the rationale for omission of such provisions from such order, and a plan and timeline to compile any information necessary to address such provisions through such order.

(d) TREATMENT OF NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.—

(1) IN GENERAL.—Any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) that was submitted to the Secretary pursuant to section 330.14 of title

21, Code of Federal Regulations, as such provisions were in effect immediately prior to the date of enactment date of this Act, shall be extinguished as of such date of enactment, subject to paragraph (2).

(2) ORDER REQUEST.—Nothing in paragraph (1) precludes the submission of an order request under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act, with respect to a drug that was the subject of an application extinguished under paragraph (1).

SEC. 1005. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN OTC COUGH AND COLD DRUGS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary of Health and Human Services shall, beginning not later than 1 year after the date of enactment of this Act, annually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a letter describing the progress of the Food and Drug Administration—

(1) in evaluating the cough and cold monograph described in subsection (b) with respect to children under age 6; and

(2) as appropriate, revising such cough and cold monograph to address such children through the order process under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drugs containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations thereof) are generally recognized as safe and effective, as specified in part 341 of title 21, Code of Federal Regulations (as in effect immediately prior to the date of enactment of this Act), and included in an order deemed to be established under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(c) DURATION OF AUTHORITY.—The requirement under subsection (a) shall terminate as of the date of a letter submitted by the Secretary of Health and Human Services pursuant to such subsection in which the Secretary indicates that the Food and Drug Administration has completed its evaluation and revised, in a final order, as applicable, the cough and cold monograph as described in subsection (a)(2).

SEC. 1006. TECHNICAL CORRECTIONS.

(a) IMPORTS AND EXPORTS.—Section 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking ''subparagraph'' each place such term appears and inserting ''paragraph''.

(b) FDA REAUTHORIZATION ACT OF 2017.—

(1) IN GENERAL.—Section 905(b)(4) of the FDA Reauthorization Act of 2017 (Public Law115–52) is amended by striking ''Section 744H(e)(2)(B)'' and inserting ''Section 744H(f)(2)(B)''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as of the enactment of the FDA Reauthorization Act of 2017 (Public Law 115–52).

TITLE II—USER FEES

SEC. 2001. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Over-the-Counter Monograph User Fee Act of 2018''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on

Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 2002. FEES RELATING TO OVER-THE-COUNTER DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by inserting after part 9 the following:

"PART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

"SEC. 744L. DEFINITIONS.

''In this part:

''(1) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(2) The term 'contract manufacturing organization facility' means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such fa-

cility directly to wholesalers, retailers, or consumers in the United States.

''(3) The term 'costs of resources allocated for OTC monograph drug activities' means the expenses in connection with OTC monograph drug activities for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and costs related to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(D) collecting fees under section 744M and accounting for resources allocated for OTC monograph drug activities.

''(4) The term 'FDA establishment identifier' is the unique number automatically generated by Food

and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

''(5) The term 'OTC monograph drug' means a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

''(6) The term 'OTC monograph drug activities' means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with such products, including the following activities:

''(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

''(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

''(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

''(iii) all OTC monograph drug development and review activities, including intra-agency collaboration;

''(iv) regulation and policy development activities related to OTC monograph drugs;

''(v) development of product standards for products subject to review and evaluation;

''(vi) meetings referred to in section 505G(i);

''(vii) review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and

''(viii) regulatory science activities related to OTC monograph drugs.

''(B) Inspections related to OTC monograph drugs.

''(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

''(D) Safety activities with respect to OTC monograph drugs, including—

''(i) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

''(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

''(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases.

''(E) Other activities necessary for implementation of section 505G.

''(7) The term 'OTC monograph order request' means a request for an order submitted under section 505G(b)(5).

''(8) The term 'Tier 1 OTC monograph order request' means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

''(9)(A) The term 'Tier 2 OTC monograph order request' means, subject to subparagraph (B), an OTC monograph order request for—

"(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

"(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

"(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A);

"(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

"(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

"(vi) addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

"(B) The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any OTC

monograph order request as a Tier 2 OTC monograph order request (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 505G.

''(10)(A) The term 'OTC monograph drug facility' means a foreign or domestic business or other entity that—

''(i) is—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

''(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

''(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, testing, or placement of outer packaging on packages con-

taining multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

''(B) For purposes of subparagraph (A)(i)(II), separate buildings or locations within close proximity are considered to be at one geographic location or address if the activities conducted in such buildings or locations are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) under a single FDA establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet criteria specified in subparagraph (A), but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(11) The term 'OTC monograph drug meeting' means any meeting regarding the content of a proposed OTC monograph order request.

''(12) The term 'person' includes an affiliate of a person.

''(13) The terms 'requestor' and 'sponsor' have the meanings given such terms in section 505G.

''SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES.

''(a) TYPES OF FEES.—Beginning with fiscal year 2019, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) FACILITY FEE.—

''(A) IN GENERAL.—Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

''(B) EXCEPTIONS.—

''(i) A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

"(I) has ceased all activities related to OTC monograph drugs prior to January 31, 2019, for the first program year, and December 31 of the fiscal year for subsequent fiscal years; and

"(II) has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

"(ii) The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

"(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

"(D) DUE DATE.—

"(i) FOR FIRST PROGRAM YEAR.—For fiscal year 2019, the facility fees required under subparagraph (A) shall be due 45 calendar days after publication of the Fed-

eral Register notice provided for under subsection (c)(4)(A).

''(ii) SUBSEQUENT FISCAL YEARS.—For each fiscal year after fiscal year 2019, the facility fees required under subparagraph (A) shall be due on the later of—

''(I) the first business day of June of such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(2) OTC MONOGRAPH ORDER REQUEST FEE.—

''(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

''(i) for a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and

''(ii) for a Tier 2 OTC monograph order request, $100,000 adjusted for infla-

tion for the fiscal year (as determined under subsection (c)(1)(B)).

''(B) DUE DATE.—The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

''(C) EXCEPTION FOR CERTAIN SAFETY CHANGES.—A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

''(i) a contraindication, warning, or precaution;

''(ii) a statement about risk associated with misuse or abuse; or

''(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

''(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request ini-

tially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

''(E) REFUND OF FEE IF ORDER REQUEST REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.

''(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC monograph order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

''(G) REFUND OF FEE IF ORDER REQUEST WITHDRAWN.—If an order request is withdrawn

after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

''(3) REFUNDS.—

''(A) IN GENERAL.—Other than refunds provided pursuant to any of subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) except as provided in subparagraph (B).

''(B) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

''(b) FEE REVENUE AMOUNTS.—

''(1) FISCAL YEAR 2019.—For fiscal year 2019, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for fiscal year 2019 (as determined under paragraph (3));

''(B) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2)); and

''(C) additional direct cost adjustments (as determined under subsection (c)(3)).

''(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2020 through 2023, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

''(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if

applicable (as determined under subsection (c)(2));

"(D) additional direct cost adjustments (as determined under subsection (c)(3)); and

"(E) additional dollar amounts for each fiscal year as follows:

"(i) $7,000,000 for fiscal year 2020.

"(ii) $6,000,000 for fiscal year 2021.

"(iii) $7,000,000 for fiscal year 2022.

"(iv) $3,000,000 for fiscal year 2023.

"(3) ANNUAL BASE REVENUE.—For purposes of paragraphs (1)(A) and (2)(A), the dollar amount of the annual base revenue for a fiscal year shall be—

"(A) for fiscal year 2019, $8,000,000; and

"(B) for fiscal years 2020 through 2023, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

"(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

"(1) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue

for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

"(i) such annual base revenue for the fiscal year under subsection (b)(2); and

"(ii) the inflation adjustment percentage under subparagraph (C).

"(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

"(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

"(ii) the inflation adjustment percentage under subparagraph (C).

"(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

"(i) for each of fiscal years 2020 and 2021, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Balti-

more, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data; and

''(ii) for each of fiscal years 2022 and 2023, the sum of—

''(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and

''(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3

years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

''(2) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2019 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

''(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

''(i) 3 weeks for fiscal year 2019;

''(ii) 7 weeks for fiscal year 2020;

''(iii) 10 weeks for fiscal year 2021;

''(iv) 10 weeks for fiscal year 2022; and

"(v) 10 weeks for fiscal year 2023.

"(C) DECREASE.—If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

"(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (4) establishing fee revenue and fees for the fiscal year involved.

"(3) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees for purposes of subsection (b)(2)(D) by an amount equal to—

"(A) $14,000,000 for fiscal year 2019;

"(B) $7,000,000 for fiscal year 2020;

"(C) $4,000,000 for fiscal year 2021;

"(D) $3,000,000 for fiscal year 2022; and

"(E) $3,000,000 for fiscal year 2023.

"(4) ANNUAL FEE SETTING.—

"(A) FISCAL YEAR 2019.—The Secretary shall, not later than the second Monday in March of 2019—

"(i) establish OTC monograph drug facility fees for fiscal year 2019 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

"(ii) publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.

"(B) SUBSEQUENT FISCAL YEARS.—The Secretary shall, not later than the second Monday in March of each fiscal year that begins after September 30, 2019—

"(i) establish for each such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

"(I) OTC monograph drug facility fees under subsection (a)(1); and

''(II) OTC monograph order request fees under subsection (a)(2); and

''(ii) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.

''(d) IDENTIFICATION OF FACILITIES.—Each person that owns an OTC monograph drug facility shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year—

''(1) be submitted as part of the requirements for drug establishment registration set forth in section 510; and

''(2) include for each such facility, at a minimum, identification of the facility's business operation as that of an OTC monograph drug facility.

''(e) EFFECT OF FAILURE TO PAY FEES.—

''(1) OTC MONOGRAPH DRUG FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list.

''(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(ff).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.

''(2) ORDER REQUESTS.—An OTC monograph order request submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person under this section have been paid.

''(3) MEETINGS.—A person subject to fees under this section shall be considered ineligible for OTC monograph drug meetings until all such fees owed by such person have been paid.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are au-

thorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for OTC monograph drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraph (C), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activi-

ties), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

''(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs funded by appropriations and allocated for OTC monograph drug activities are not more than 15 percent below the level specified in such subparagraph.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2019), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2019 through 2023, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''SEC. 744N. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2019, and not later than 120 calendar days after the end of each fiscal year thereafter for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 2001(b) of the Over-the-Counter Mono-

graph Safety, Innovation, and Reform Act of 2018 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals.

''(b) FISCAL REPORT.—Not later than 120 calendar days after the end of fiscal year 2019 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the internet website of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2023, and for the reauthorization of this part

for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2023, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.".

Passed the House of Representatives December 20, 2018.

Attest:

Clerk.

115TH CONGRESS
2D SESSION

H. R. 7328

AN ACT

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, to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved drug application, and for other purposes.