

115TH CONGRESS
2^D 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.

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

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

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

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

Sec. 1. Short title; table of contents.

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

Sec. 100. References in division.

**TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY
 STRATEGY**

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

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

Sec. 202. Amendments to preparedness and response programs.

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

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

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

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

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

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

Sec. 209. Report on adequate national blood supply.

Sec. 210. Report on the public health preparedness and response capabilities and capacities of hospitals, long-term care facilities, and other health care facilities.

TITLE III—REACHING ALL COMMUNITIES

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

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

Sec. 303. Considerations for at-risk individuals.

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

Sec. 305. National advisory committees on disasters.

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

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

- Sec. 401. Assistant Secretary for Preparedness and Response.
- Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
- Sec. 403. Strategic National Stockpile.
- Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.
- Sec. 405. Reporting on the Federal Select Agent Program.

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

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

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

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

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Reauthorizations and extensions.
- Sec. 702. Location of materials in the stockpile.
- Sec. 703. Cybersecurity.
- Sec. 704. Strategy and report.
- Sec. 705. Technical amendments.

DIVISION B—OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM

- Sec. 1000. Short title; references in division.

TITLE I—OTC DRUG REVIEW

- Sec. 1001. Regulation of certain nonprescription drugs that are marketed without an approved drug application.
- Sec. 1002. Misbranding.
- Sec. 1003. Drugs excluded from the over-the-counter drug review.
- Sec. 1004. Treatment of Sunscreen Innovation Act.
- Sec. 1005. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.
- Sec. 1006. Technical corrections.

TITLE II—USER FEES

Sec. 2001. Short title; finding.

Sec. 2002. Fees relating to over-the-counter drugs.

1 **DIVISION A—PANDEMIC AND**
 2 **ALL-HAZARDS PREPARED-**
 3 **NESS AND ADVANCING INNO-**
 4 **VATION**

5 **SEC. 100. REFERENCES IN DIVISION.**

6 Except as otherwise specified—

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

11 (2) any reference to “this Act” contained in
 12 this division shall be treated as referring only to the
 13 provisions of this division.

14 **TITLE I—STRENGTHENING THE**
 15 **NATIONAL HEALTH SECURITY**
 16 **STRATEGY**

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

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

19 (1) in subsection (a)—

20 (A) in paragraph (1)—

21 (i) by striking “2014” and inserting
 22 “2018”; and

23 (ii) by striking the second sentence
 24 and inserting the following: “Such Na-

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

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

21 (C) in paragraph (3)—

22 (i) by striking “2009” and inserting
23 “2022”;

24 (ii) by inserting “(including gaps in
25 the environmental health and animal

1 health workforces, as applicable), describ-
2 ing the status of such workforce” after
3 “gaps in such workforce”;

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

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

11 (2) in subsection (b)—

12 (A) in paragraph (2)—

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

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

22 (iii) by adding at the end the fol-
23 lowing:

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

25 (B) in paragraph (3)—

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

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

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

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

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

1 rectly related to public health emergency prepared-
2 ness and response capabilities, as applicable.

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

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

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

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

15 “(k) EVALUATION.—

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

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

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

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

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

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

22 “(D) recommendations, as applicable and
23 appropriate, to improve evidence-based bench-
24 marks and objective standards to more accu-
25 rately assess the ability of entities receiving

1 awards under this section to better achieve the
2 goals under this section and section 2802.”.

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

8 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
9 **SPONSE PROGRAMS.**

10 (a) **COOPERATIVE AGREEMENT APPLICATIONS FOR**
11 **IMPROVING STATE AND LOCAL PUBLIC HEALTH SECUR-**
12 **ITY.**—Section 319C–1 (42 U.S.C. 247d–3a) is amend-
13 ed—

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

17 (2) in subsection (b)(2)(A)—

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

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

1 (C) by inserting after clause (vi) the fol-
2 lowing:

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

8 (D) in clause (ix), as so redesignated, by
9 striking “; and” and inserting a semicolon; and
10 (E) by adding at the end the following:

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

17 “(xii) a description of how, as appro-
18 priate and practicable, the entity will in-
19 clude critical infrastructure partners, such
20 as utility companies within the entity’s ju-
21 risdiction, in planning pursuant to this
22 subparagraph to help ensure that critical
23 infrastructure will remain functioning dur-
24 ing, or return to function as soon as prac-
25 ticable after, a public health emergency;”.

1 (b) EXCEPTION RELATING TO APPLICATION OF CER-
2 TAIN REQUIREMENTS.—

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

5 (A) in paragraph (5)—

6 (i) in the matter preceding subpara-
7 graph (A), by striking “Beginning with fis-
8 cal year 2009” and inserting “Beginning
9 with fiscal year 2019”; and

10 (ii) in subparagraph (A)—

11 (I) by striking “for the imme-
12 diately preceding fiscal year” and in-
13 sserting “for either of the 2 imme-
14 diately preceding fiscal years”; and

15 (II) by striking “2008” and in-
16 sserting “2018”; and

17 (B) in paragraph (6), by amending sub-
18 paragraph (A) to read as follows:

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

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

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

7 “(ii) For no more than 1 of the first
8 2 fiscal years immediately following the
9 third consecutive fiscal year in which an
10 entity experienced such a failure, in lieu of
11 applying clause (i), an amount equal to 15
12 percent of the amount the entity was eligi-
13 ble to receive for the respective fiscal
14 year.”.

15 (2) EFFECTIVE DATE.—The amendments made
16 by paragraph (1) shall apply with respect to cooper-
17 ative agreements awarded on or after the date of en-
18 actment of this Act.

19 (c) PARTNERSHIP FOR STATE AND REGIONAL HOS-
20 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
21 Section 319C-2 (42 U.S.C. 247d-3b) is amended—

22 (1) in subsection (a)—

23 (A) by inserting “, acting through the As-
24 sistant Secretary for Preparedness and Re-
25 sponse,” after “The Secretary”; and

1 (B) by striking “preparedness for public
2 health emergencies” and inserting “prepared-
3 ness for, and response to, public health emer-
4 gencies in accordance with subsection (c)”;

5 (2) in subsection (b)(1)(A)—

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

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

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

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

14 (3) in subsection (d)—

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

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

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

23 (5) in subsection (g)(2)—

24 (A) by striking “Partnerships” and insert-
25 ing “Coalitions”;

1 (B) by striking “partnerships” and insert-
2 ing “coalitions”; and

3 (C) by inserting “and response” after
4 “preparedness”; and

5 (6) in subsection (i)(1)—

6 (A) by striking “An entity” and inserting
7 “A coalition”; and

8 (B) by striking “such partnership” and in-
9 serting “such coalition”.

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

19 (e) PARTNERSHIP FOR STATE AND REGIONAL HOS-
20 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-
21 TIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is
22 amended—

23 (1) by amending paragraph (1) to read as fol-
24 lows:

25 “(1) IN GENERAL.—

1 “(A) AUTHORIZATION OF APPROPRIA-
2 TIONS.—For purposes of carrying out this sec-
3 tion and section 319C–3, in accordance with
4 subparagraph (B), there is authorized to be ap-
5 propriated \$385,000,000 for each of fiscal years
6 2019 through 2023.

7 “(B) RESERVATION OF AMOUNTS FOR RE-
8 GIONAL SYSTEMS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (b) GAO REPORT TO CONGRESS.—

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

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

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

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

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

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

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

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

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

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

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

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

22 (F) the Secretary of Veterans Affairs.

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

1 this paragraph, a coalition shall include information on the
2 progress that the coalition has made toward the implemen-
3 tation of section 319C–3 (or barriers to progress, if
4 any).”.

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

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

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

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

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

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

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

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

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

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

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

15 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
16 **FOR TRAUMA READINESS GRANT PROGRAM**

17 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
18 **TRAUMA READINESS GRANT PROGRAM.**

19 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-
20 GRAM.—

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

1 trauma teams to provide, on a full-time basis, trauma
2 care and related acute care at such trauma centers.
3

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

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

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

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

19 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-
20 MENT PROGRAM.—

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

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

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

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

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

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

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

17 “(c) GRANT REQUIREMENTS.—

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

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

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

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

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

21 “(e) REPORTING REQUIREMENTS.—

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

1 submit to the Secretary and the Secretary of De-
2 fense a report for such year that includes informa-
3 tion on—

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

8 “(B) the ability to maintain the integration
9 of the military trauma providers or teams of
10 providers as part of the trauma center, includ-
11 ing the financial effect of such grant on the
12 trauma center;

13 “(C) the educational effect on resident
14 trainees in centers where military trauma teams
15 are assigned;

16 “(D) any research conducted during such
17 year supported by such grant; and

18 “(E) any other information required by the
19 Secretaries for the purpose of evaluating the ef-
20 fect of such grant.

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

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

3 “(A) maintaining military trauma care
4 providers’ readiness and ability to respond to
5 and treat battlefield injuries;

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

8 “(C) the capability of trauma centers and
9 military trauma care providers to increase med-
10 ical surge capacity, including as a result of a
11 large scale event;

12 “(D) the ability of grant recipients to
13 maintain the integration of the military trauma
14 providers or teams of providers as part of the
15 trauma center;

16 “(E) efforts to incorporate military trauma
17 care providers into operational exercises and
18 training and drills for public health emer-
19 gencies; and

20 “(F) the capability of military trauma care
21 providers to participate as part of a medical re-
22 sponse during or in advance of a public health
23 emergency, as determined by the Secretary, or
24 a mass casualty incident.

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

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

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

9 “(B) Such trauma center utilizes a risk-ad-
10 justed benchmarking system and metrics to
11 measure performance, quality, and patient out-
12 comes.

13 “(C) Such trauma center demonstrates a
14 need for integrated military trauma care pro-
15 viders to maintain or improve the trauma clin-
16 ical capability of such trauma center.

17 “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-
18 TER.—The term ‘eligible high acuity trauma center’
19 means a Level I trauma center that satisfies each of
20 the following:

21 “(A) Such trauma center has an agree-
22 ment with the Secretary of Defense to enable
23 military trauma teams to provide trauma care
24 and related acute care at such trauma center.

1 “(B) At least 20 percent of patients treat-
2 ed at such trauma center in the most recent 3-
3 month period for which data are available are
4 treated for a major trauma at such trauma cen-
5 ter.

6 “(C) Such trauma center utilizes a risk-ad-
7 justed benchmarking system and metrics to
8 measure performance, quality, and patient out-
9 comes.

10 “(D) Such trauma center is an academic
11 training center—

12 “(i) affiliated with a medical school;

13 “(ii) that maintains residency pro-
14 grams and fellowships in critical trauma
15 specialties and subspecialties, and provides
16 education and supervision of military trau-
17 ma team members according to those spe-
18 cialties and subspecialties; and

19 “(iii) that undertakes research in the
20 prevention and treatment of traumatic in-
21 jury.

22 “(E) Such trauma center serves as a med-
23 ical and public health preparedness and re-
24 sponse leader for its community, such as by
25 participating in a partnership for State and re-

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

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

6 “(4) MILITARY TRAUMA TEAM.—The term
7 ‘military trauma team’ means a complete military
8 trauma team consisting of military trauma care pro-
9 viders.

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

19 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there are authorized to be appro-
21 priated \$11,500,000 for each of fiscal years 2019 through
22 2023.”.

1 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
2 **UATIONAL AWARENESS AND BIOSURVEIL-**
3 **LANCE CAPABILITIES.**

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

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

10 (2) in subsection (a)—

11 (A) in the subsection heading, by striking
12 “FACILITIES; CAPACITIES” and inserting “IN
13 GENERAL”;

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

17 (C) in paragraph (3), in the matter pre-
18 ceding subparagraph (A), by striking “expand,
19 enhance, and improve” and inserting “expand,
20 improve, enhance, and appropriately maintain”;
21 and

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

23 “(4) STUDY OF RESOURCES FOR FACILITIES
24 AND CAPACITIES.—Not later than June 1, 2022, the
25 Comptroller General of the United States shall con-
26 duct a study on Federal spending in fiscal years

1 2013 through 2018 for activities authorized under
2 this subsection. Such study shall include a review
3 and assessment of obligations and expenditures di-
4 rectly related to each activity under paragraphs (2)
5 and (3), including a specific accounting of, and de-
6 lineation between, obligations and expenditures in-
7 curred for the construction, renovation, equipping,
8 and security upgrades of facilities and associated
9 contracts under this subsection, and the obligations
10 and expenditures incurred to establish and improve
11 the situational awareness and biosurveillance net-
12 work under subsection (b), and shall identify the
13 agency or agencies incurring such obligations and
14 expenditures.”;

15 (3) in subsection (b)—

16 (A) in the subsection heading, by striking
17 “NATIONAL” and inserting “ESTABLISHMENT
18 OF SYSTEMS OF PUBLIC HEALTH”;

19 (B) in paragraph (1)(B), by inserting “im-
20 munization information systems,” after “cen-
21 ters,”; and

22 (C) in paragraph (2)—

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

1 (ii) by inserting “and in a form read-
2 ily usable for analytical approaches” after
3 “in a secure manner”; and

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

6 “(3) STANDARDS.—

7 “(A) IN GENERAL.—Not later than 1 year
8 after the date of the enactment of the Pan-
9 demic and All-Hazards Preparedness and Ad-
10 vancing Innovation Act of 2018, the Secretary,
11 in cooperation with health care providers, State,
12 local, tribal, and territorial public health offi-
13 cials, and relevant Federal agencies (including
14 the Office of the National Coordinator for
15 Health Information Technology and the Na-
16 tional Institute of Standards and Technology),
17 shall, as necessary, adopt technical and report-
18 ing standards, including standards for inter-
19 operability as defined by section 3000, for net-
20 works under paragraph (1) and update such
21 standards as necessary. Such standards shall be
22 made available on the internet website of the
23 Department of Health and Human Services, in
24 a manner that does not compromise national se-
25 curity.

1 “(B) DEFERENCE TO STANDARDS DEVEL-
2 OPMENT ORGANIZATIONS.—In adopting and im-
3 plementing standards under this subsection and
4 subsection (c), the Secretary shall give def-
5 erence to standards published by standards de-
6 velopment organizations and voluntary con-
7 sensus-based standards entities.”;

8 (4) in subsection (c)—

9 (A) in paragraph (1)—

10 (i) by striking “Not later than 2 years
11 after the date of enactment of the Pan-
12 demic and All-Hazards Preparedness Re-
13 authorization Act of 2013, the Secretary”
14 and inserting “The Secretary”;

15 (ii) by inserting “, and improve as ap-
16 plicable and appropriate,” after “shall es-
17 tablish”;

18 (iii) by striking “of rapid” and insert-
19 ing “of, rapid”; and

20 (iv) by striking “such connectivity”
21 and inserting “such interoperability”;

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

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

4 “(A) facilitate coordination among agencies
5 within the Department of Health and Human
6 Services that provide, or have the potential to
7 provide, information and data to, and analyses
8 for, the situational awareness and biosurveil-
9 lance network under paragraph (1), including
10 coordination among relevant agencies related to
11 health care services, the facilitation of health
12 information exchange (including the Office of
13 the National Coordinator for Health Informa-
14 tion Technology), and public health emergency
15 preparedness and response; and

16 “(B) consult with the Secretary of Agri-
17 culture, the Secretary of Commerce (and the
18 Director of the National Institute of Standards
19 and Technology), the Secretary of Defense, the
20 Secretary of Homeland Security, the Secretary
21 of Veterans Affairs, and the heads of other
22 Federal agencies, as the Secretary determines
23 appropriate.”;

24 (C) in paragraph (3)—

1 (i) by redesignating subparagraphs
2 (A) through (E) as clauses (i) through (v),
3 respectively, and adjusting the margins ac-
4 cordingly;

5 (ii) in clause (iv), as so redesign-
6 nated—

7 (I) by inserting “immunization
8 information systems,” after “poison
9 control,”; and

10 (II) by striking “and clinical lab-
11 oratories” and inserting “, clinical
12 laboratories, and public environmental
13 health agencies”;

14 (iii) by striking “The network” and
15 inserting the following:

16 “(A) IN GENERAL.—The network”; and

17 (iv) by adding at the end the fol-
18 lowing:

19 “(B) REVIEW.—Not later than 2 years
20 after the date of the enactment of the Pan-
21 demic and All-Hazards Preparedness and Ad-
22 vancing Innovation Act of 2018 and every 6
23 years thereafter, the Secretary shall conduct a
24 review of the elements described in subpara-
25 graph (A). Such review shall include a discus-

1 sion of the addition of any elements pursuant to
2 clause (v), including elements added to advanc-
3 ing new technologies, and identify any chal-
4 lenges in the incorporation of elements under
5 subparagraph (A). The Secretary shall provide
6 such review to the congressional committees of
7 jurisdiction.”;

8 (D) in paragraph (5)—

9 (i) by redesignating subparagraphs
10 (A) through (D) as clauses (i) through
11 (iv), respectively, and adjusting the mar-
12 gins accordingly;

13 (ii) by striking “In establishing” and
14 inserting the following:

15 “(A) IN GENERAL.—In establishing”;

16 (iii) by adding at the end the fol-
17 lowing:

18 “(B) PUBLIC MEETING.—

19 “(i) IN GENERAL.—Not later than
20 180 days after the date of enactment of
21 the Pandemic and All-Hazards Prepared-
22 ness and Advancing Innovation Act of
23 2018, the Secretary shall convene a public
24 meeting for purposes of discussing and
25 providing input on the potential goals,

1 functions, and uses of the network de-
2 scribed in paragraph (1) and incorporating
3 the elements described in paragraph
4 (3)(A).

5 “(ii) EXPERTS.—The public meeting
6 shall include representatives of relevant
7 Federal agencies (including representatives
8 from the Office of the National Coordi-
9 nator for Health Information Technology
10 and the National Institute of Standards
11 and Technology); State, local, tribal, and
12 territorial public health officials; stake-
13 holders with expertise in biosurveillance
14 and situational awareness; stakeholders
15 with expertise in capabilities relevant to
16 biosurveillance and situational awareness,
17 such as experts in informatics and data
18 analytics (including experts in prediction,
19 modeling, or forecasting); and other rep-
20 resentatives as the Secretary determines
21 appropriate.

22 “(iii) TOPICS.—Such public meeting
23 shall include a discussion of—

24 “(I) data elements, including
25 minimal or essential data elements,

1 that are voluntarily provided for such
2 network, which may include elements
3 from public health and public and pri-
4 vate health care entities, to the extent
5 practicable;

6 “(II) standards and implementa-
7 tion specifications that may improve
8 the collection, analysis, and interpre-
9 tation of data during a public health
10 emergency;

11 “(III) strategies to encourage the
12 access, exchange, and use of informa-
13 tion;

14 “(IV) considerations for State,
15 local, tribal, and territorial capabilities
16 and infrastructure related to data ex-
17 change and interoperability;

18 “(V) privacy and security protec-
19 tions provided at the Federal, State,
20 local, tribal, and territorial levels, and
21 by nongovernmental stakeholders; and

22 “(VI) opportunities for the incor-
23 poration of innovative technologies to
24 improve the network.”; and

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

3 (I) in clause (i), as so redesign-
4 nated—

5 (aa) by striking “as deter-
6 mined” and inserting “as adopt-
7 ed”; and

8 (bb) by inserting “and the
9 National Institute of Standards
10 and Technology” after “Office of
11 the National Coordinator for
12 Health Information Technology”;

13 (II) in clause (iii), as so redesign-
14 nated, by striking “; and” and insert-
15 ing a semicolon;

16 (III) in clause (iv), as so redesign-
17 nated, by striking the period and in-
18 serting “; and”; and

19 (IV) by adding at the end the fol-
20 lowing:

21 “(v) pilot test standards and imple-
22 mentation specifications, consistent with
23 the process described in section
24 3002(b)(3)(C), which State, local, tribal,
25 and territorial public health entities may

1 utilize, on a voluntary basis, as a part of
2 the network.”;

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

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

7 “(6) STRATEGY AND IMPLEMENTATION
8 PLAN.—

9 “(A) IN GENERAL.—Not later than 18
10 months after the date of enactment of the Pan-
11 demic and All-Hazards Preparedness and Ad-
12 vancing Innovation Act of 2018, the Secretary
13 shall submit to the congressional committees of
14 jurisdiction a coordinated strategy and an ac-
15 companying implementation plan that—

16 “(i) is informed by the public meeting
17 under paragraph (5)(B);

18 “(ii) includes a review and assessment
19 of existing capabilities of the network and
20 related infrastructure, including input pro-
21 vided by the public meeting under para-
22 graph (5)(B);

23 “(iii) identifies and demonstrates the
24 measurable steps the Secretary will carry
25 out to—

1 “(I) develop, implement, and
2 evaluate the network described in
3 paragraph (1), utilizing elements de-
4 scribed in paragraph (3)(A);

5 “(II) modernize and enhance bio-
6 surveillance activities, including strat-
7 egies to include innovative tech-
8 nologies and analytical approaches
9 (including prediction and forecasting
10 for pandemics and all-hazards) from
11 public and private entities;

12 “(III) improve information shar-
13 ing, coordination, and communication
14 among disparate biosurveillance sys-
15 tems supported by the Department of
16 Health and Human Services, includ-
17 ing the identification of methods to
18 improve accountability, better utilize
19 resources and workforce capabilities,
20 and incorporate innovative tech-
21 nologies within and across agencies;
22 and

23 “(IV) test and evaluate capabili-
24 ties of the interoperable network of

1 systems to improve situational aware-
2 ness and biosurveillance capabilities;

3 “(iv) includes performance measures
4 and the metrics by which performance
5 measures will be assessed with respect to
6 the measurable steps under clause (iii);
7 and

8 “(v) establishes dates by which each
9 measurable step under clause (iii) will be
10 implemented.

11 “(B) ANNUAL BUDGET PLAN.—Not later
12 than 2 years after the date of enactment of the
13 Pandemic and All-Hazards Preparedness and
14 Advancing Innovation Act of 2018 and on an
15 annual basis thereafter, in accordance with the
16 strategy and implementation plan under this
17 paragraph, the Secretary shall, taking into ac-
18 count recommendations provided by the Na-
19 tional Biodefense Science Board, develop a
20 budget plan based on the strategy and imple-
21 mentation plan under this section. Such budget
22 plan shall include—

23 “(i) a summary of resources pre-
24 viously expended to establish, improve, and
25 utilize the nationwide public health situa-

1 tional awareness and biosurveillance net-
2 work under paragraph (1);

3 “(ii) estimates of costs and resources
4 needed to establish and improve the net-
5 work under paragraph (1) according to the
6 strategy and implementation plan under
7 subparagraph (A);

8 “(iii) the identification of gaps and in-
9 efficiencies in nationwide public health sit-
10 uational awareness and biosurveillance ca-
11 pabilities, resources, and authorities need-
12 ed to address such gaps; and

13 “(iv) a strategy to minimize and ad-
14 dress such gaps and improve inefficien-
15 cies.”;

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

17 (i) in subparagraph (A), by inserting
18 “(taking into account zoonotic disease, in-
19 cluding gaps in scientific understanding of
20 the interactions between human, animal,
21 and environmental health)” after “human
22 health”;

23 (ii) in subparagraph (B)—

1 (I) by inserting “and gaps in sur-
2 veillance programs” after “surveil-
3 lance programs”; and

4 (II) by striking “; and” and in-
5 serting a semicolon;

6 (iii) in subparagraph (C)—

7 (I) by inserting “, animal health
8 organizations related to zoonotic dis-
9 ease,” after “health care entities”;
10 and

11 (II) by striking the period and
12 inserting “; and”; and

13 (iv) by adding at the end the fol-
14 lowing:

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

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

20 “(8) SITUATIONAL AWARENESS AND BIO-
21 SURVEILLANCE AS A NATIONAL SECURITY PRI-
22 ORITY.—The Secretary, on a periodic basis as appli-
23 cable and appropriate, shall meet with the Director
24 of National Intelligence to inform the development

1 and capabilities of the nationwide public health situ-
2 ational awareness and biosurveillance network.”;

3 (5) in subsection (d)—

4 (A) in paragraph (1)—

5 (i) by inserting “environmental health
6 agencies,” after “public health agencies,”;

7 and

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

10 and

11 (B) in paragraph (2)—

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

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

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

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

21 (C) by striking paragraph (5) and insert-
22 ing the following:

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

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

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

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

8 “(f) PERSONNEL AUTHORITIES.—

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

12 “(A) appoint highly qualified individuals to
13 scientific or professional positions at the Cen-
14 ters for Disease Control and Prevention, not to
15 exceed 30 such employees at any time (specific
16 to positions authorized by this subsection), with
17 expertise in capabilities relevant to biosurveil-
18 lance and situational awareness, such as experts
19 in informatics and data analytics (including ex-
20 perts in prediction, modeling, or forecasting),
21 and other related scientific or technical fields;
22 and

23 “(B) compensate individuals appointed
24 under subparagraph (A) in the same manner
25 and subject to the same terms and conditions in

1 which individuals appointed under 9903 of title
2 5, United States Code, are compensated, with-
3 out regard to the provisions of chapter 51 and
4 subchapter III of chapter 53 of such title relat-
5 ing to classification and General Schedule pay
6 rates.

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

11 “(g) TIMELINE.—The Secretary shall accomplish the
12 purposes under subsections (b) and (c) no later than Sep-
13 tember 30, 2023, and shall provide a justification to the
14 congressional committees of jurisdiction for any missed or
15 delayed implementation of measurable steps identified
16 under subsection (c)(6)(A)(iii).

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

1 plicable and appropriate, on necessary improvements to
2 the biosurveillance and situational awareness network.”.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
4 section (i) of section 319D (42 U.S.C. 247d–4), as reded-
5 icated by subsection (a)(6), is amended by striking
6 “\$138,300,000 for each of fiscal years 2014 through
7 2018” and inserting “\$161,800,000 for each of fiscal
8 years 2019 through 2023”.

9 (c) BIOLOGICAL THREAT DETECTION REPORT.—The
10 Secretary of Health and Human Services shall, in coordi-
11 nation with the Secretary of Defense and the Secretary
12 of Homeland Security, not later than 180 days after the
13 date of enactment of this Act, report to the Committee
14 on Energy and Commerce, the Committee on Armed Serv-
15 ices, and the Committee on Homeland Security of the
16 House of Representatives and the Committee on Health,
17 Education, Labor, and Pensions, the Committee on Armed
18 Services, and the Committee on Homeland Security and
19 Governmental Affairs of the Senate on the state of Fed-
20 eral biological threat detection efforts, including the fol-
21 lowing—

22 (1) an identification of technological, oper-
23 ational, and programmatic successes and failures of
24 domestic detection programs supported by Federal
25 departments and agencies for intentionally-intro-

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

3 (2) a description of Federal efforts to facilitate
4 the exchange of information related to the informa-
5 tion described in paragraph (1) among Federal de-
6 partments and agencies that utilize biological threat
7 detection technology;

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

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

14 (B) recover live biological agents from col-
15 lection devices;

16 (C) determine the geographical distribution
17 of biological agents;

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

21 (E) provide advanced molecular diagnostics
22 to State, local, tribal, and territorial public
23 health and other laboratories that support bio-
24 logical threat detection activities;

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

3 (5) a description of efforts by Federal depart-
4 ments and agencies that utilize biological threat de-
5 tection technology to collaborate with State, local,
6 tribal, and territorial public health laboratories and
7 other users of biological threat detection systems, in-
8 cluding collaboration regarding the development of—

9 (A) biological threat detection require-
10 ments or standards;

11 (B) a standardized integration strategy;

12 (C) training requirements or guidelines;

13 (D) guidelines for a coordinated public
14 health response, including preparedness capa-
15 bilities, and, as applicable, for coordination with
16 public health surveillance systems; and

17 (E) a coordinated environmental remedi-
18 ation plan, as applicable; and

19 (6) recommendations related to research, ad-
20 vanced research, development, and procurement for
21 Federal departments and agencies to improve and
22 enhance biological threat detection systems, includ-
23 ing recommendations on the transfer of biological
24 threat detection technology among Federal depart-
25 ments and agencies, as necessary and appropriate.

1 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**
2 **HEALTH EMERGENCY RAPID RESPONSE**
3 **FUND.**

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

5 (1) in subsection (b)—

6 (A) in paragraph (1)—

7 (i) in the first sentence, by inserting
8 “or if the Secretary determines there is the
9 significant potential for a public health
10 emergency, to allow the Secretary to rap-
11 idly respond to the immediate needs result-
12 ing from such public health emergency or
13 potential public health emergency” before
14 the period; and

15 (ii) by inserting “The Secretary shall
16 plan for the expedited distribution of funds
17 to appropriate agencies and entities.” after
18 the first sentence;

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

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

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

25 “(A) facilitate coordination between and
26 among Federal, State, local, tribal, and terri-

1 torial entities and public and private health
2 care entities that the Secretary determines may
3 be affected by a public health emergency or po-
4 tential public health emergency referred to in
5 paragraph (1) (including communication of
6 such entities with relevant international enti-
7 ties, as applicable);

8 “(B) make grants, provide for awards,
9 enter into contracts, and conduct supportive in-
10 vestigations pertaining to a public health emer-
11 gency or potential public health emergency, in-
12 cluding further supporting programs under sec-
13 tion 319C-1, 319C-2, or 319C-3;

14 “(C) facilitate and accelerate, as applica-
15 ble, advanced research and development of secu-
16 rity countermeasures (as defined in section
17 319F-2), qualified countermeasures (as defined
18 in section 319F-1), or qualified pandemic or
19 epidemic products (as defined in section 319F-
20 3), that are applicable to the public health
21 emergency or potential public health emergency
22 under paragraph (1);

23 “(D) strengthen biosurveillance capabilities
24 and laboratory capacity to identify, collect, and
25 analyze information regarding such public

1 health emergency or potential public health
2 emergency, including the systems under section
3 319D;

4 “(E) support initial emergency operations
5 and assets related to preparation and deploy-
6 ment of intermittent disaster response per-
7 sonnel under section 2812 and the Medical Re-
8 serve Corps under section 2813; and

9 “(F) carry out other activities, as the Sec-
10 retary determines applicable and appropriate.”;
11 and

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

14 “(4) REVIEW.—Not later than 2 years after the
15 date of enactment of the Pandemic and All-Hazards
16 Preparedness and Advancing Innovation Act of
17 2018, the Secretary, in coordination with the Assist-
18 ant Secretary for Preparedness and Response, shall
19 conduct a review of the Fund under this section and
20 provide recommendations to the Committee on
21 Health, Education, Labor, and Pensions and the
22 Committee on Appropriations of the Senate and the
23 Committee on Energy and Commerce and the Com-
24 mittee on Appropriations of the House of Represent-

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

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

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

11 “(B) submit to the Committee on Health,
12 Education, Labor, and Pensions of the Senate
13 and the Committee on Energy and Commerce
14 of the House of Representatives a report on
15 such review, including recommendations related
16 to such review, as applicable.”; and

17 (2) in subsection (c)—

18 (A) by inserting “rapidly respond to public
19 health emergencies or potential public health
20 emergencies and” after “used to”; and

21 (B) by striking “section.” and inserting
22 “Act or funds otherwise provided for emergency
23 response.”.

1 **SEC. 207. IMPROVING ALL-HAZARDS PREPAREDNESS AND**
2 **RESPONSE BY PUBLIC HEALTH EMERGENCY**
3 **VOLUNTEERS.**

4 (a) IN GENERAL.—Section 319I (42 U.S.C. 247d–
5 7b) is amended—

6 (1) in the section heading, by striking
7 “**HEALTH PROFESSIONS VOLUNTEERS**” and in-
8 serting “**VOLUNTEER HEALTH PROFESSIONAL**”;

9 (2) in subsection (a), by adding at the end the
10 following: “Such health care professionals may in-
11 clude members of the National Disaster Medical
12 System, members of the Medical Reserve Corps, and
13 individual health care professionals.”;

14 (3) in subsection (i) by adding at the end “In
15 order to inform the development of such mechanisms
16 by States, the Secretary shall make available infor-
17 mation and material provided by States that have
18 developed mechanisms to waive the application of li-
19 censing requirements to applicable health profes-
20 sionals seeking to provide medical services during a
21 public health emergency. Such information shall be
22 made publicly available in a manner that does not
23 compromise national security.”; and

24 (4) in subsection (k) by striking “2014 through
25 2018” and inserting “2019 through 2023”.

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

5 “(iv) a description of the mechanism the
6 entity will implement to utilize the Emergency
7 Management Assistance Compact, or other mu-
8 tual aid agreement, for medical and public
9 health mutual aid, and, as appropriate, the ac-
10 tivities such entity will implement pursuant to
11 section 319I to improve enrollment and coordi-
12 nation of volunteer health care professionals
13 seeking to provide medical services during a
14 public health emergency, which may include—

15 “(I) providing a public method of
16 communication for purposes of volunteer
17 coordination (such as a phone number);

18 “(II) providing for optional registra-
19 tion to participate in volunteer services
20 during processes related to State medical
21 licensing, registration, or certification or
22 renewal of such licensing, registration or
23 certification; or

24 “(III) other mechanisms as the State
25 determines appropriate;”.

1 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
2 **TEER HEALTH CARE PROFESSIONALS.**

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

5 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**
6 **ING A PUBLIC HEALTH EMERGENCY.**

7 “(a) LIMITATION ON LIABILITY.—Notwithstanding
8 any other provision of law, a health care professional who
9 is a member of the Medical Reserve Corps under section
10 2813 or who is included in the Emergency System for Ad-
11 vance Registration of Volunteer Health Professionals
12 under section 319I and who—

13 “(1) is responding—

14 “(A) to a public health emergency deter-
15 mined under section 319(a), during the initial
16 period of not more than 90 days (as determined
17 by the Secretary) of the public health emer-
18 gency determination (excluding any period cov-
19 ered by a renewal of such determination); or

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

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

3 “(A) during the initial period of a deter-
4 mination or declaration described in paragraph
5 (1) and related to the treatment of individuals
6 in need of health care services due to such pub-
7 lic health emergency, major disaster, or emer-
8 gency;

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

11 “(C) in the health care professional’s ca-
12 pacity as a member of the Medical Reserve
13 Corps or a professional included in the Emer-
14 gency System for Advance Registration of Vol-
15 unteer Health Professionals under section 319I;
16 and

17 “(D) in the course of providing services
18 that are within the scope of the license, reg-
19 istration, or certification of the professional, as
20 defined by the State of licensure, registration,
21 or certification; and

22 “(3) prior to the rendering of such act or omis-
23 sion, was authorized by the State’s authorization of
24 deploying such State’s Emergency System for Ad-
25 vance Registration of Volunteer Health Professionals

1 described in section 319I or the Medical Reserve
2 Corps established under section 2813, to provide
3 health care services,
4 shall be subject only to the State liability laws of the State
5 in which such act or omission occurred, in the same man-
6 ner and to the same extent as a similar health care profes-
7 sional who is a resident of such State would be subject
8 to such State laws, except with respect to the licensure,
9 registration, and certification of such individual.

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

14 “(c) PREEMPTION.—This section shall supersede the
15 laws of any State that would subject a health care profes-
16 sional described in subsection (a) to the liability laws of
17 any State other than the State liability laws to which such
18 individual is subject pursuant to such subsection.

19 “(d) DEFINITIONS.—In this section:

20 “(1) The term ‘health care professional’ means
21 an individual licensed, registered, or certified under
22 Federal or State laws or regulations to provide
23 health care services.

24 “(2) The term ‘health care services’ means any
25 services provided by a health care professional, or by

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

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

5 “(B) the assessment or care of the health
6 of human beings.

7 “(e) EFFECTIVE DATE.—

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

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

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

19 (1) the number of health care providers who
20 register under the Emergency System for Advance
21 Registration of Volunteer Health Professionals
22 under section 319I of the Public Health Service Act
23 (42 U.S.C. 247d–7b) in advance to provide services
24 during a public health emergency;

1 (2) the number of health care providers who are
2 credentialed to provide services during the period of
3 a public health emergency declaration, including
4 those who are credentialed through programs estab-
5 lished in the Emergency System for Advance Reg-
6 istration of Volunteer Health Professionals under
7 such section 319I and those credentialed by authori-
8 ties within the State in which the emergency oc-
9 curred;

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

18 (4) the Emergency System for Advance Reg-
19 istration of Volunteer Health Professionals program
20 in States, including whether physician or medical
21 groups, associations, or other relevant provider orga-
22 nizations utilize such program for purposes of volun-
23 teering during public health emergencies.

1 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
2 **PLY.**

3 Not later than 1 year after the date of the enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to Congress a report containing recommenda-
6 tions related to maintaining an adequate national blood
7 supply, including—

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

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

13 (3) implementation of the transfusion trans-
14 mission monitoring system; and

15 (4) other measures to promote safety and inno-
16 vation, such as the development, use, or implementa-
17 tion of new technologies, processes, and procedures
18 to improve the safety and reliability of the blood
19 supply.

20 **SEC. 210. REPORT ON THE PUBLIC HEALTH PREPARED-**
21 **NESS AND RESPONSE CAPABILITIES AND CA-**
22 **PACITIES OF HOSPITALS, LONG-TERM CARE**
23 **FACILITIES, AND OTHER HEALTH CARE FA-**
24 **CILITIES.**

25 (a) STUDY.—

1 (1) IN GENERAL.—Not later than one year
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services shall enter
4 into an agreement with an appropriate entity to con-
5 duct a study regarding the public health prepared-
6 ness and response capabilities and medical surge ca-
7 pacities of hospitals, long-term care facilities, and
8 other health care facilities to prepare for, and re-
9 spond to, public health emergencies, including nat-
10 ural disasters.

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

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

19 (A) an evaluation of the current bench-
20 marks and objective standards, as applicable,
21 related to programs that support hospitals,
22 long-term care facilities, and other health care
23 facilities, and their effect on improving public
24 health preparedness and response capabilities
25 and medical surge capacities, including the

1 Hospital Preparedness Program, the Public
2 Health Emergency Preparedness cooperative
3 agreements, and the Regional Health Care
4 Emergency Preparedness and Response Sys-
5 tems under section 319C–3 of the Public
6 Health Service Act (as added by section 203);

7 (B) the identification of gaps in prepared-
8 ness, including with respect to such benchmarks
9 and objective standards, such as those identified
10 during recent public health emergencies, for
11 hospitals, long-term care facilities, and other
12 health care facilities to address future potential
13 public health threats;

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

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

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

5 (E) an evaluation of current public health
6 preparedness and response capabilities and
7 medical surge capacities related to at-risk indi-
8 viduals during public health emergencies, in-
9 cluding an identification of gaps in such pre-
10 paredness as they relate to such individuals.

11 (b) REPORT.—

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

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

21 (A) describe the findings and conclusions
22 of the evaluation conducted pursuant to sub-
23 section (a); and

24 (B) provide recommendations for improv-
25 ing public health preparedness and response ca-

1 pability and medical surge capacity for hos-
2 pitals, long-term care facilities, and other health
3 care facilities, including—

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

9 (ii) identifying best practices for im-
10 proving public health preparedness and re-
11 sponse programs and medical surge capae-
12 ity at hospitals, long-term care facilities,
13 and other health care facilities, including
14 recommendations for the evaluation under
15 subparagraphs (C) and (D) of subsection
16 (a)(3).

17 **TITLE III—REACHING ALL** 18 **COMMUNITIES**

19 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-** 20 **GENCY RESPONSE WORKFORCE.**

21 (a) NATIONAL DISASTER MEDICAL SYSTEM.—

22 (1) STRENGTHENING THE NATIONAL DISASTER
23 MEDICAL SYSTEM.—Clause (ii) of section
24 2812(a)(3)(A) (42 U.S.C. 300hh–11(a)(3)(A)) is
25 amended to read as follows:

1 “(ii) be present at locations, and for
2 limited periods of time, specified by the
3 Secretary on the basis that the Secretary
4 has determined that a location is at risk of
5 a public health emergency during the time
6 specified, or there is a significant potential
7 for a public health emergency.”.

8 (2) REVIEW OF THE NATIONAL DISASTER MED-
9 ICAL SYSTEM.—Section 2812(b)(2) (42 U.S.C.
10 300hh–11(b)(2)) is amended to read as follows:

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

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

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

24 “(ii) an assessment of the available
25 workforce of the intermittent disaster re-

1 response personnel described in subsection
2 (c);

3 “(iii) the capacity of the workforce de-
4 scribed in clause (ii) to respond to all haz-
5 ards, including capacity to simultaneously
6 respond to multiple public health emer-
7 gencies and the capacity to respond to a
8 nationwide public health emergency;

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

11 “(v) gaps that may exist in such
12 workforce and recommendations for ad-
13 dressing such gaps.

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

20 (3) NOTIFICATION OF SHORTAGE.—Section
21 2812(c) (42 U.S.C. 300hh–11(c)) is amended by
22 adding at the end the following:

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

1 of the National Disaster Medical System is insuffi-
2 cient to address a public health emergency or poten-
3 tial public health emergency, the Secretary shall sub-
4 mit to the congressional committees of jurisdiction a
5 notification detailing—

6 “(A) the impact such shortage could have
7 on meeting public health needs and emergency
8 medical personnel needs during a public health
9 emergency; and

10 “(B) any identified measures to address
11 such shortage.

12 “(4) CERTAIN APPOINTMENTS.—

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

1 “(B) SUNSET.—The authority under this
2 paragraph shall expire on September 30,
3 2021.”.

4 (4) AUTHORIZATION OF APPROPRIATIONS.—
5 Section 2812(g) (42 U.S.C. 300hh–11(g)) is amend-
6 ed by striking “\$52,700,000 for each of fiscal years
7 2014 through 2018” and inserting “\$57,400,000 for
8 each of fiscal years 2019 through 2023”.

9 (b) VOLUNTEER MEDICAL RESERVE CORPS.—

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

16 (2) AUTHORIZATION OF APPROPRIATIONS.—
17 Section 2813(i) (42 U.S.C. 300hh–15(i)) is amended
18 by striking “2014 through 2018” and inserting
19 “2019 through 2023”.

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

23 (1) in subsection (a)—

24 (A) in paragraph (1)—

1 (i) by inserting “or preparedness and
2 response activities, including rapid re-
3 sponse to public health emergencies and
4 significant public health threats” after
5 “conduct prevention activities”; and

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

8 (B) in paragraph (2)(B), by striking “3
9 years” and inserting “2 years”; and
10 (2) in subsection (c)—

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

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

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

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

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

3 (1) IN GENERAL.—Section 2812(c) (42 U.S.C.
4 300hh–11(c)), as amended by subsection (a)(3), is
5 further amended by adding at the end the following:

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

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

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

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

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

24 “(E) an individual appointed to the Na-
25 tional Disaster Medical System under section

1 2812 of the Public Health Service Act (42
2 U.S.C. 300hh–11) who is performing official
3 duties of the Department of Health and Human
4 Services, if those official duties are—

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

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

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

17 (e) MISSION READINESS REPORT TO CONGRESS.—

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

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

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

10 (A) the number of health care providers
11 who have volunteered to provide health care
12 services during a public health emergency, in-
13 cluding members of the National Disaster Med-
14 ical System, the Disaster Medical Assistant
15 Teams, the Medical Reserve Corps, and other
16 volunteer health care professionals in the
17 verification network pursuant to section 319I of
18 the Public Health Service Act (42 U.S.C.
19 247d–7b);

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

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

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

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

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

20 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
21 **PREPAREDNESS AND RESPONSE.**

22 (a) COORDINATION OF PREPAREDNESS.—Section
23 2811(b)(5) (42 U.S.C. 300hh–10(b)(5)) is amended by
24 adding at the end the following: “Such logistical support
25 shall include working with other relevant Federal, State,

1 local, tribal, and territorial public health officials and pri-
2 vate sector entities to identify the critical infrastructure
3 assets, systems, and networks needed for the proper func-
4 tioning of the health care and public health sectors that
5 need to be maintained through any emergency or disaster,
6 including entities capable of assisting with, responding to,
7 and mitigating the effect of a public health emergency,
8 including a public health emergency determined by the
9 Secretary pursuant to section 319(a) or an emergency or
10 major disaster declared by the President under the Robert
11 T. Stafford Disaster Relief and Emergency Assistance Act
12 or the National Emergencies Act, including by estab-
13 lishing methods to exchange critical information and de-
14 liver products consumed or used to preserve, protect, or
15 sustain life, health, or safety, and sharing of specialized
16 expertise.”.

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

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

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

1 duct a study on issues that have the potential to ad-
2 versely affect the handling and rapid delivery of
3 medical countermeasures to individuals during public
4 health emergencies occurring in the United States.

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

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

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

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

5 (1) by striking “this section and sections 319C–
6 1, 319F, and 319L,” and inserting “this Act,”; and

7 (2) by striking “special” and inserting “access
8 or functional”.

9 (b) COUNTERMEASURE CONSIDERATIONS.—Section
10 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

11 (1) by striking “elderly” and inserting “older
12 adults”; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 (2) in subsection (d)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 “(J) The Secretary of Education.

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

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

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

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

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

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

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

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

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

9 “(d) MEMBERSHIP.—

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

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

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

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

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

3 “(D) The Commissioner of Food and
4 Drugs.

5 “(E) The Director of the National Insti-
6 tutes of Health.

7 “(F) The Administrator of the Centers for
8 Medicare & Medicaid Services.

9 “(G) The Administrator of the Administra-
10 tion for Community Living.

11 “(H) The Administrator of the Federal
12 Emergency Management Agency.

13 “(I) The Under Secretary for Health of
14 the Department of Veterans Affairs.

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

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

23 “(L) Representatives of such other Federal
24 agencies (such as the Department of Energy
25 and the Department of Homeland Security) as

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

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

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

9 “(g) SUNSET.—

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

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

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

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

23 “(a) ESTABLISHMENT.—The Secretary, in consulta-
24 tion with the Secretary of Homeland Security, shall estab-
25 lish a national advisory committee to be known as the Na-

1 tional Advisory Committee on Individuals with Disabilities
2 and Disasters (referred to in this section as the ‘Advisory
3 Committee’).

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

5 “(1) provide advice and consultation with re-
6 spect to activities carried out pursuant to section
7 2814, as applicable and appropriate;

8 “(2) evaluate and provide input with respect to
9 the medical, public health, and accessibility needs of
10 individuals with disabilities related to preparation
11 for, response to, and recovery from all-hazards emer-
12 gencies; and

13 “(3) provide advice and consultation with re-
14 spect to State emergency preparedness and response
15 activities, including related drills and exercises pur-
16 suant to the preparedness goals under section
17 2802(b).

18 “(c) MEMBERSHIP.—

19 “(1) IN GENERAL.—The Secretary, in consulta-
20 tion with such other heads of agencies and depart-
21 ments as appropriate, shall appoint not more than
22 17 members to the Advisory Committee. In appoint-
23 ing such members, the Secretary shall ensure that
24 the total membership of the Advisory Committee is
25 an odd number.

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

6 “(A) The Assistant Secretary for Pre-
7 paredness and Response.

8 “(B) The Administrator of the Administra-
9 tion for Community Living.

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

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

14 “(E) The Commissioner of Food and
15 Drugs.

16 “(F) The Director of the National Insti-
17 tutes of Health.

18 “(G) The Administrator of the Federal
19 Emergency Management Agency.

20 “(H) The Chair of the National Council on
21 Disability.

22 “(I) The Chair of the United States Access
23 Board.

24 “(J) The Under Secretary for Health of
25 the Department of Veterans Affairs.

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

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

11 “(M) At least 2 individuals with a dis-
12 ability with expertise in disaster planning, pre-
13 paredness, response, or recovery for individuals
14 with disabilities.

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

18 “(e) DISABILITY DEFINED.—For purposes of this
19 section, the term ‘disability’ has the meaning given such
20 term in section 3 of the Americans with Disabilities Act
21 of 1990.

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

25 “(g) SUNSET.—

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

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

7 (d) ADVISORY COMMITTEE COORDINATION.—Sub-
8 title B of title XXVIII (42 U.S.C. 300hh et seq.), as
9 amended by subsection (c), is further amended by insert-
10 ing after section 2811C the following:

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

12 “(a) IN GENERAL.—The Secretary shall coordinate
13 duties and activities authorized under sections 2811A,
14 2811B, and 2811C, and make efforts to reduce unneces-
15 sary or duplicative reporting, or unnecessary duplicative
16 meetings and recommendations under such sections, as
17 practicable. Members of the advisory committees author-
18 ized under such sections, or their designees, shall annually
19 meet to coordinate any recommendations, as appropriate,
20 that may be similar, duplicative, or overlapping with re-
21 spect to addressing the needs of children, seniors, and in-
22 dividuals with disabilities during public health emer-
23 gencies. If such coordination occurs through an in-person
24 meeting, it shall not be considered the required in-person

1 meetings under any of sections 2811A(e), 2811B(e), or
2 2811C(d).

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

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

15 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
16 **AND DRILLS.**

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

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

14 **TITLE IV—PRIORITIZING A**
15 **THREAT-BASED APPROACH**

16 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
17 **RESPONSE.**

18 Section 2811(b) (42 U.S.C. 300hh–10(b)) is amend-
19 ed—

20 (1) in the matter preceding paragraph (1) by
21 inserting “utilize experience related to public health
22 emergency preparedness and response, biodefense,
23 medical countermeasures, and other relevant topics
24 to” after “shall”; and

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

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

16 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
17 **TERMEASURES ENTERPRISE.**

18 (a) IN GENERAL.—Title XXVIII is amended by in-
19 serting after section 2811 (42 U.S.C. 300hh–10) the fol-
20 lowing:

21 **“SEC. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL**
22 **COUNTERMEASURES ENTERPRISE.**

23 “(a) IN GENERAL.—The Secretary shall establish the
24 Public Health Emergency Medical Countermeasures En-
25 terprise (referred to in this section as the ‘PHEMCE’).

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

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

6 “(1) The Assistant Secretary for Preparedness
7 and Response.

8 “(2) The Director of the Centers for Disease
9 Control and Prevention.

10 “(3) The Director of the National Institutes of
11 Health.

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

13 “(5) The Secretary of Defense.

14 “(6) The Secretary of Homeland Security.

15 “(7) The Secretary of Agriculture.

16 “(8) The Secretary of Veterans Affairs.

17 “(9) The Director of National Intelligence.

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

1 “(c) FUNCTIONS.—

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

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

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

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

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

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

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

20 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
21 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
22 TATION PLAN.—Section 2811(d) (42 U.S.C. 300hh–
23 10(d)) is amended—

24 (1) in paragraph (1)—

1 (A) by striking “Not later than 180 days
2 after the date of enactment of this subsection,
3 and every year thereafter” and inserting “Not
4 later than March 15, 2020, and biennially
5 thereafter”; and

6 (B) by striking “Director of the Bio-
7 medical” and all that follows through “Food
8 and Drugs” and inserting “Public Health
9 Emergency Medical Countermeasures Enter-
10 prise established under section 2811–1”; and

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

13 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

14 (a) IN GENERAL.—Section 319F–2(a) (42 U.S.C.
15 247d–6b(a)) is amended—

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

18 (2) in paragraph (1)—

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

22 (B) by inserting “and optimize” after
23 “provide for”;

24 (C) by inserting “and, as informed by ex-
25 isting recommendations of, or consultations

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

8 (D) by striking the second sentence;

9 (3) by inserting after paragraph (1) the fol-
10 lowing:

11 “(2) THREAT-BASED REVIEW.—

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

1 sions and the Committee on Appropriations of
2 the Senate and the Committee on Energy and
3 Commerce and the Committee on Appropria-
4 tions of the House of Representatives, in a
5 manner that does not compromise national se-
6 curity.

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

12 “(i) information regarding—

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

17 “(II) planning considerations for
18 appropriate manufacturing capacity
19 and capability to meet the goals of
20 such additions or modifications (with-
21 out disclosing proprietary informa-
22 tion), including consideration of the
23 effect such additions or modifications
24 may have on the availability of such

1 products and ancillary medical sup-
2 plies in the health care system;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(5) GAO REPORT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (c) AUTHORIZATION OF APPROPRIATIONS, STRA-
25 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) (42

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

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

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

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

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

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

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

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

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

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

18 “(f) PROTECTION OF NATIONAL SECURITY FROM
19 THREATS.—

20 “(1) IN GENERAL.—In carrying out subsection
21 (b)(3), the Assistant Secretary for Preparedness and
22 Response shall implement strategic initiatives or ac-
23 tivities to address threats, including pandemic influ-
24 enza and which may include a chemical, biological,
25 radiological, or nuclear agent (including any such

1 agent with a significant potential to become a pan-
2 demic), that pose a significant level of risk to public
3 health and national security based on the character-
4 istics of such threat. Such initiatives shall include
5 activities to—

6 “(A) accelerate and support the advanced
7 research, development, manufacturing capacity,
8 procurement, and stockpiling of counter-
9 measures, including initiatives under section
10 319L(e)(4)(F);

11 “(B) support the development and manu-
12 facturing of virus seeds, clinical trial lots, and
13 stockpiles of novel virus strains; and

14 “(C) maintain or improve preparedness ac-
15 tivities, including for pandemic influenza.

16 “(2) AUTHORIZATION OF APPROPRIATIONS.—

17 “(A) IN GENERAL.—To carry out this sub-
18 section, there is authorized to be appropriated
19 \$250,000,000 for each of fiscal years 2019
20 through 2023.

21 “(B) SUPPLEMENT, NOT SUPPLANT.—
22 Amounts appropriated under this paragraph
23 shall be used to supplement and not supplant
24 funds provided under sections 319L(d) and
25 319F–2(g).

1 “(C) DOCUMENTATION REQUIRED.—The
2 Assistant Secretary for Preparedness and Re-
3 sponse, in accordance with subsection (b)(7),
4 shall document amounts expended for purposes
5 of carrying out this subsection, including
6 amounts appropriated under the heading ‘Pub-
7 lic Health and Social Services Emergency
8 Fund’ under the heading ‘Office of the Sec-
9 retary’ under title II of division H of the Con-
10 solidated Appropriations Act, 2018 (Public Law
11 115–141) and allocated to carrying out section
12 319L(c)(4)(F).”.

13 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
14 **PROGRAM.**

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

16 (1) by striking “The Secretary” and inserting
17 the following:

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

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

20 “(2) IMPLEMENTATION OF RECOMMENDATIONS
21 OF THE FEDERAL EXPERTS SECURITY ADVISORY
22 PANEL AND THE FAST TRACK ACTION COMMITTEE
23 ON SELECT AGENT REGULATIONS.—

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

1 demic and All-Hazards Preparedness and Ad-
2 vancing Innovation Act of 2018, the Secretary
3 shall report to the congressional committees of
4 jurisdiction on the implementation of rec-
5 ommendations of the Federal Experts Security
6 Advisory Panel concerning the select agent pro-
7 gram.

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

16 **TITLE V—INCREASING COMMU-**
17 **NICATION IN MEDICAL COUN-**
18 **TERMEASURE ADVANCED RE-**
19 **SEARCH AND DEVELOPMENT**

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

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

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

25 (2) in subparagraph (A)—

1 (A) in clause (ii), by striking “; and” and
2 inserting “;”; and

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

5 “(iii) procurement, stockpiling, main-
6 tenance, and potential replenishment (in-
7 cluding manufacturing capabilities) of all
8 products in the Strategic National Stock-
9 pile;

10 “(iv) the availability of technologies
11 that may assist in the advanced research
12 and development of countermeasures and
13 opportunities to use such technologies to
14 accelerate and navigate challenges unique
15 to countermeasure research and develop-
16 ment; and

17 “(v) potential deployment, distribu-
18 tion, and utilization of medical counter-
19 measures; development of clinical guidance
20 and emergency use instructions for the use
21 of medical countermeasures; and, as appli-
22 cable, potential post-deployment activities
23 related to medical countermeasures;”;

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

1 (4) by inserting after subparagraph (C), the fol-
2 lowing:

3 “(D) identify the full range of anticipated
4 medical countermeasure needs related to re-
5 search and development, procurement, and
6 stockpiling, including the potential need for in-
7 dications, dosing, and administration tech-
8 nologies, and other countermeasure needs as
9 applicable and appropriate;”.

10 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
11 **MEASURE NOTIFICATIONS.**

12 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL
13 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42
14 U.S.C. 247d–6b(c)(2)(C)) is amended by striking “The
15 Secretary and the Homeland Security Secretary shall
16 promptly notify the appropriate committees of Congress”
17 and inserting “The Secretary and the Secretary of Home-
18 land Security shall send to Congress, on an annual basis,
19 all current material threat determinations and shall
20 promptly notify the Committee on Health, Education,
21 Labor, and Pensions and the Committee on Homeland Se-
22 curity and Governmental Affairs of the Senate and the
23 Committee on Energy and Commerce and the Committee
24 on Homeland Security of the House of Representatives”.

1 (b) CONTRACTING COMMUNICATION.—Section 319F–
2 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–6b(c)(7)(B)(ii)(III))
3 is amended by adding at the end the following: “The Sec-
4 retary shall notify the vendor within 90 days of a deter-
5 mination by the Secretary to renew, extend, or terminate
6 such contract.”.

7 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
8 **PLANS.**

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

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

13 (2) by inserting after paragraph (2) the fol-
14 lowing:

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

19 “(A) the process by which an applicant
20 may submit a request for a regulatory manage-
21 ment plan;

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

24 “(C) the information required for the sub-
25 mission of such request;

1 “(D) a description of the types of develop-
2 ment milestones and performance targets that
3 could be discussed and included in such plans;
4 and

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

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

9 (A) by striking “paragraph (4)(A)” and in-
10 serting “paragraph (5)(A)”; and

11 (B) by striking “paragraph (4)(B)” and
12 inserting “paragraph (5)(B)”; and

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

16 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
17 **VELOPMENT AUTHORITY AND THE BIO-**
18 **SHIELD SPECIAL RESERVE FUND.**

19 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
20 319F–2(g)(1) (42 U.S.C. 247d–6b(g)(1)) is amended—

21 (1) by striking “\$2,800,000,000 for the period
22 of fiscal years 2014 through 2018” and inserting
23 “\$7,100,000,000 for the period of fiscal years 2019
24 through 2028, to remain available until expended”;
25 and

1 (2) by striking the second sentence.

2 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
3 DEVELOPMENT AUTHORITY.—Section 319L(d)(2) (42
4 U.S.C. 247d–7e(d)(2)) is amended by striking
5 “\$415,000,000 for each of fiscal years 2014 through
6 2018” and inserting “\$611,700,000 for each of fiscal
7 years 2019 through 2023”.

8 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**
9 **BIOTIC RESISTANCE.**

10 (a) ADVISORY COUNCIL.—The Secretary of Health
11 and Human Services (referred to in this section as the
12 “Secretary”) may continue the Presidential Advisory
13 Council on Combating Antibiotic-Resistant Bacteria, re-
14 ferred to in this section as the “Advisory Council”.

15 (b) DUTIES.—The Advisory Council shall advise and
16 provide information and recommendations to the Sec-
17 retary regarding programs and policies intended to reduce
18 or combat antibiotic-resistant bacteria that may present
19 a public health threat and improve capabilities to prevent,
20 diagnose, mitigate, or treat such resistance. Such advice,
21 information, and recommendations may be related to im-
22 proving—

23 (1) the effectiveness of antibiotics;

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

1 for combating or reducing antibiotic resistance, in-
2 cluding new treatments, rapid point-of-care
3 diagnostics, alternatives to antibiotics, including al-
4 ternatives to animal antibiotics, and antimicrobial
5 stewardship activities;

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

9 (4) education for health care providers and the
10 public with respect to up-to-date information on an-
11 tibiotic resistance and ways to reduce or combat
12 such resistance to antibiotics related to humans and
13 animals;

14 (5) methods to prevent or reduce the trans-
15 mission of antibiotic-resistant bacterial infections,
16 including stewardship programs; and

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

20 (c) MEETINGS AND COORDINATION.—

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

1 (2) COORDINATION.—The Advisory Council
2 shall, to the greatest extent practicable, coordinate
3 activities carried out by the Council with the Anti-
4 microbial Resistance Task Force established under
5 section 319E(a) of the Public Health Service Act
6 (42 U.S.C. 247d–5(a)).

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

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

1 **TITLE VI—ADVANCING TECH-**
2 **NOLOGIES FOR MEDICAL**
3 **COUNTERMEASURES**

4 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

5 Section 319L(c)(4)(D)(iii) (42 U.S.C. 247d–
6 7e(c)(4)(D)(iii)) is amended by striking “and platform
7 technologies” and inserting “platform technologies, tech-
8 nologies to administer countermeasures, and technologies
9 to improve storage and transportation of counter-
10 measures”.

11 **SEC. 602. UPDATING DEFINITIONS OF OTHER TRANS-**
12 **ACTIONS.**

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

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

16 (2) in subsection (c)(5)(A)—

17 (A) in clause (i), by striking “under this
18 subsection” and all that follows through “Code”
19 and inserting “(as defined in subsection (a)(3))
20 under this subsection”; and

21 (B) in clause (ii)—

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

24 “(I) IN GENERAL.—To the max-
25 imum extent practicable, competitive

1 procedures shall be used when enter-
2 ing into transactions to carry out
3 projects under this subsection.”; and

4 (ii) in subclause (II)—

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

7 (II) by striking “senior procure-
8 ment executive for the Department
9 (as designated for purpose of section
10 16(c) of the Office of Federal Pro-
11 curement Policy Act (41 U.S.C.
12 414(c))” and inserting “Assistant
13 Secretary for Financial Resources”;
14 and

15 (III) by striking “senior procure-
16 ment executive under” and inserting
17 “Assistant Secretary for Financial Re-
18 sources under”.

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

20 (a) IN GENERAL.—The purpose of this section (in-
21 cluding section 565B of the Federal Food, Drug, and Cos-
22 metic Act, as added by subsection (b)) is to support and
23 advance the development or manufacture of security coun-
24 termeasures, qualified countermeasures, and qualified
25 pandemic or epidemic products by facilitating and encour-

1 aging submission of data and information to support the
2 development of such products, and through clarifying the
3 authority to cross-reference to data and information pre-
4 viously submitted to the Secretary of Health and Human
5 Services (referred to in this section as the “Secretary”),
6 including data and information submitted to medical coun-
7 termeasure master files or other master files.

8 (b) **MEDICAL COUNTERMEASURE MASTER FILES.**—
9 Chapter V of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
11 tion 565A the following:

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

13 “(a) **APPLICABILITY OF REFERENCE.**—

14 “(1) **IN GENERAL.**—A person may submit data
15 and information in a master file to the Secretary
16 with the intent to reference, or to authorize, in writ-
17 ing, another person to reference, such data or infor-
18 mation to support a medical countermeasure submis-
19 sion (including a supplement or amendment to any
20 such submission), without requiring the master file
21 holder to disclose the data and information to any
22 such persons authorized to reference the master file.
23 Such data and information shall be available for ref-
24 erence by the master file holder or by a person au-
25 thorized by the master file holder, in accordance

1 with applicable privacy and confidentiality protocols
2 and regulations.

3 “(2) REFERENCE OF CERTAIN MASTER
4 FILES.—In the case that data or information within
5 a medical countermeasure master file is used only to
6 support the conditional approval of an application
7 filed under section 571, such master file may be re-
8 lied upon to support the effectiveness of a product
9 that is the subject of a subsequent medical counter-
10 measure submission only if such application is sup-
11 plemented by additional data or information to sup-
12 port review and approval in a manner consistent
13 with the standards applicable to such review and ap-
14 proval for such countermeasure, qualified counter-
15 measure, or qualified pandemic or epidemic product.

16 “(b) MEDICAL COUNTERMEASURE MASTER FILE
17 CONTENT.—

18 “(1) IN GENERAL.—A master file under this
19 section may include data or information to sup-
20 port—

21 “(A) the development of medical counter-
22 measure submissions to support the approval,
23 licensure, classification, clearance, conditional
24 approval, or authorization of one or more secu-
25 rity countermeasures, qualified counter-

1 measures, or qualified pandemic or epidemic
2 products; and

3 “(B) the manufacture of security counter-
4 measures, qualified countermeasures, or quali-
5 fied pandemic or epidemic products.

6 “(2) REQUIRED UPDATES.—The Secretary may
7 require, as appropriate, that the master file holder
8 ensure that the contents of such master file are up-
9 dated during the time such master file is referenced
10 for a medical countermeasure submission.

11 “(c) SPONSOR REFERENCE.—

12 “(1) IN GENERAL.—Each incorporation of data
13 or information within a medical countermeasure
14 master file shall describe the incorporated material
15 in a manner in which the Secretary determines ap-
16 propriate and that permits the review of such infor-
17 mation within such master file without necessitating
18 re-submission of such data or information. Master
19 files shall be submitted in an electronic format in ac-
20 cordance with sections 512(b)(4), 571(a)(4), and
21 745A, as applicable, and as specified in applicable
22 guidance.

23 “(2) REFERENCE BY A MASTER FILE HOLD-
24 ER.—A master file holder that is the sponsor of a
25 medical countermeasure submission shall notify the

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

4 “(3) REFERENCE BY AN AUTHORIZED PER-
5 SON.—A person submitting an application for review
6 may, where the Secretary determines appropriate,
7 incorporate by reference all or part of the contents
8 of a medical countermeasure master file, if the mas-
9 ter file holder authorizes the incorporation in writ-
10 ing.

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

13 “(1) IN GENERAL.—The Secretary shall provide
14 the master file holder with a written notification in-
15 dicating that the Secretary has reviewed and relied
16 upon specified data or information within a master
17 file and the purposes for which such data or infor-
18 mation was incorporated by reference if the Sec-
19 retary has reviewed and relied upon such specified
20 data or information to support the approval, classi-
21 fication, conditional approval, clearance, licensure, or
22 authorization of a security countermeasure, qualified
23 countermeasure, or qualified pandemic or epidemic
24 product. The Secretary may rely upon the data and
25 information within the medical countermeasure mas-

1 ter file for which such written notification was pro-
2 vided in additional applications, as applicable and
3 appropriate and upon the request of the master file
4 holder so notified in writing or by an authorized per-
5 son of such holder.

6 “(2) CERTAIN APPLICATIONS.—If the Secretary
7 has reviewed and relied upon specified data or infor-
8 mation within a medical countermeasure master file
9 to support the conditional approval of an application
10 under section 571 to subsequently support the ap-
11 proval, clearance, licensure, or authorization of a se-
12 curity countermeasure, qualified countermeasure, or
13 qualified pandemic or epidemic product, the Sec-
14 retary shall provide a brief written description to the
15 master file holder regarding the elements of the ap-
16 plication fulfilled by the data or information within
17 the master file and how such data or information
18 contained in such application meets the standards of
19 evidence under subsection (c) or (d) of section 505,
20 subsection (d) of section 512, or section 351 of the
21 Public Health Service Act (as applicable), which
22 shall not include any trade secret or confidential
23 commercial information.

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

1 “(1) limit the authority of the Secretary to ap-
2 prove, license, clear, conditionally approve, or au-
3 thorize drugs, biological products, or devices pursu-
4 ant to, as applicable, this Act or section 351 of the
5 Public Health Service Act (as such applicable Act is
6 in effect on the day before the date of enactment of
7 the Pandemic and All-Hazards Preparedness and
8 Advancing Innovation Act of 2018), including the
9 standards of evidence, and applicable conditions, for
10 approval under the applicable Act;

11 “(2) alter the standards of evidence with re-
12 spect to approval, licensure, or clearance, as applica-
13 ble, of drugs, biological products, or devices under
14 this Act or section 351 of the Public Health Service
15 Act, including, as applicable, the substantial evi-
16 dence standards under sections 505(d) and 512(d)
17 or this Act and section 351(a) of the Public Health
18 Service Act; or

19 “(3) alter the authority of the Secretary under
20 this Act or the Public Health Service Act to deter-
21 mine the types of data or information previously
22 submitted by a sponsor or any other person that
23 may be incorporated by reference in an application,
24 request, or notification for a drug, biological prod-
25 uct, or device submitted under sections 505(i),

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

7 “(f) DEFINITIONS.—In this section:

8 “(1) The term ‘master file holder’ means a per-
9 son who submits data and information to the Sec-
10 retary with the intent to reference or authorize an-
11 other person to reference such data or information
12 to support a medical countermeasure submission, as
13 described in subsection (a).

14 “(2) The term ‘medical countermeasure submis-
15 sion’ means an investigational new drug application
16 under section 505(i), a new drug application under
17 section 505(b), or an abbreviated new drug applica-
18 tion under section 505(j) of this Act, a biological
19 product license application under section 351(a) of
20 the Public Health Service Act or a biosimilar biologi-
21 cal product license application under section 351(k)
22 of the Public Health Service Act, a new animal drug
23 application under section 512(b)(1) or abbreviated
24 new animal drug application under section
25 512(b)(2), an application for conditional approval of

1 a new animal drug under section 571, an investiga-
2 tional device application under section 520(g), an
3 application with respect to a device under section
4 515(c), a request for classification of a device under
5 section 513(f)(2), a notification with respect to a de-
6 vice under section 510(k), or a request for an emer-
7 gency use authorization under section 564 to sup-
8 port—

9 “(A) the approval, licensure, classification,
10 clearance, conditional approval, or authorization
11 of a security countermeasure, qualified counter-
12 measure, or qualified pandemic or epidemic
13 product; or

14 “(B) a new indication to an approved secu-
15 rity countermeasure, qualified countermeasure,
16 or qualified pandemic or epidemic product.

17 “(3) The terms ‘qualified countermeasure’, ‘se-
18 curity countermeasure’, and ‘qualified pandemic or
19 epidemic product’ have the meanings given such
20 terms in sections 319F–1, 319F–2, and 319F–3, re-
21 spectively, of the Public Health Service Act.”.

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

1 for Preparedness and Response, shall solicit input from
2 stakeholders, including stakeholders developing security
3 countermeasures, qualified countermeasures, or qualified
4 pandemic or epidemic products, and stakeholders devel-
5 oping technologies to assist in the development of such
6 countermeasures with respect to how the Food and Drug
7 Administration can advance the use of tools and tech-
8 nologies to support and advance the development or manu-
9 facture of security countermeasures, qualified counter-
10 measures, and qualified pandemic or epidemic products,
11 including through reliance on cross-referenced data and
12 information contained within master files and submissions
13 previously submitted to the Secretary as set forth in sec-
14 tion 565B of the Federal Food, Drug, and Cosmetic Act,
15 as added by subsection (b).

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

1 manufacture of security countermeasures, qualified coun-
2 termeasures, and qualified pandemic or epidemic products.
3 The Secretary, acting through the Commissioner of Food
4 and Drugs, shall publish the final guidance not later than
5 3 years after the enactment of this Act.

6 **SEC. 604. ANIMAL RULE REPORT.**

7 (a) STUDY.—The Comptroller General of the United
8 States shall conduct a study on the application of the re-
9 quirements under subsections (c) and (d) of section 565
10 of the of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360bbb–4) (referred to in this section as the “ani-
12 mal rule”) as a component of medical countermeasure ad-
13 vanced development under the Biomedical Advanced Re-
14 search and Development Authority and regulatory review
15 by the Food and Drug Administration. In conducting such
16 study, the Comptroller General shall examine the fol-
17 lowing:

18 (1) The extent to which advanced development
19 and review of a medical countermeasure are coordi-
20 nated between the Biomedical Advanced Research
21 and Development Authority and the Food and Drug
22 Administration, including activities that facilitate
23 appropriate and efficient design of studies to sup-
24 port approval, licensure, and authorization under the
25 animal rule, consistent with the recommendations in

1 the animal rule guidance, issued pursuant to section
2 565(c) of the Federal Food Drug and Cosmetic Act
3 (21 U.S.C. 360bbb–4(c)) and entitled “Product De-
4 velopment Under the Animal Rule: Guidance for In-
5 dustry” (issued in October 2015), to resolve discrep-
6 ancies in the design of adequate and well-controlled
7 efficacy studies conducted in animal models related
8 to the provision of substantial evidence of effective-
9 ness for the product approved, licensed, or author-
10 ized under the animal rule.

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

14 (3) The flexibility pursuant to the animal rule
15 to address variations in countermeasure development
16 and review processes, including the extent to which
17 qualified animal models are adopted and used within
18 the Food and Drug Administration in regulatory de-
19 cisionmaking with respect to medical counter-
20 measures.

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

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

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

6 (1) the Federal agencies responsible for advanc-
7 ing, reviewing, and procuring medical counter-
8 measures, including the Office of the Assistant Sec-
9 retary for Preparedness and Response, the Bio-
10 medical Advanced Research and Development Au-
11 thority, the Food and Drug Administration, and the
12 Department of Defense;

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

17 (3) other biodefense stakeholders, as applicable.

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

1 requirements under subsections (c) and (d) of section 565
2 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.
3 360bbb-4) to support and expedite the research and devel-
4 opment of medical countermeasures, as applicable.

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

10 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**
11 **NEERING TECHNOLOGIES AND THEIR POTEN-**
12 **TIAL ROLE IN NATIONAL SECURITY.**

13 (a) MEETING.—

14 (1) IN GENERAL.—Not later than 1 year after
15 the date of enactment of this Act, the Secretary of
16 Health and Human Services (referred to in this sec-
17 tion as the “Secretary”) shall convene a meeting to
18 discuss the potential role advancements in genomic
19 engineering technologies (including genome editing
20 technologies) may have in advancing national health
21 security. Such meeting shall be held in a manner
22 that does not compromise national security.

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

25 (A) shall include—

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

7 (ii) representatives from academic,
8 private, and nonprofit entities with exper-
9 tise in genome engineering technologies,
10 biopharmaceuticals, medicine, or bio-
11 defense, and other relevant stakeholders;
12 and

13 (B) may include—

14 (i) other representatives from the De-
15 partment of Health and Human Services,
16 as the Secretary determines appropriate;
17 and

18 (ii) representatives from the Depart-
19 ment of Homeland Security, the Depart-
20 ment of Defense, the Department of Agri-
21 culture, and other departments, as the Sec-
22 retary may request for the meeting.

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

1 (A) the current state of the science of
2 genomic engineering technologies related to na-
3 tional health security, including—

4 (i) medical countermeasure develop-
5 ment, including potential efficiencies in the
6 development pathway and detection tech-
7 nologies; and

8 (ii) the international and domestic
9 regulation of products utilizing genome ed-
10 iting technologies; and

11 (B) national security implications, includ-
12 ing—

13 (i) capabilities of the United States to
14 leverage genomic engineering technologies
15 as a part of the medical countermeasure
16 enterprise, including current applicable re-
17 search, development, and application ef-
18 forts underway within the Department of
19 Defense;

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

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

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

5 (b) REPORT.—Not later than 270 days after the
6 meeting described in subsection (a) is held, the Assistant
7 Secretary for Preparedness and Response shall issue a re-
8 port to the congressional committees of jurisdiction on the
9 topics discussed at such meeting, and provide rec-
10 ommendations, as applicable, to utilize innovations in
11 genomic engineering (including genome editing) and re-
12 lated technologies as a part of preparedness and response
13 activities to advance national health security. Such report
14 shall be issued in a manner that does not compromise na-
15 tional security.

16 **SEC. 606. REPORT ON VACCINES DEVELOPMENT.**

17 Not later than one year after the date of the enact-
18 ment of this Act, the Secretary of Health and Human
19 Services shall submit to the Committee on Health, Edu-
20 cation, Labor, and Pensions of the Senate and the Com-
21 mittee on Energy and Commerce of the House of Rep-
22 resentatives a report describing efforts and activities to
23 coordinate with other countries and international partners
24 during recent public health emergencies with respect to
25 the research and advanced research on, and development

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

12 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**
13 **SAFETY AND HEALTH.**

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

17 (1) in subsection (a)(1)(B)—

18 (A) by inserting “including programs to
19 address emerging infectious mosquito-borne dis-
20 eases,” after “subdivisions for control pro-
21 grams,”; and

22 (B) by inserting “or improving existing
23 control programs” before the period at the end;

24 (2) in subsection (b)—

1 (A) in paragraph (1), by inserting “, in-
2 cluding improvement,” after “operation”;

3 (B) in paragraph (2)—

4 (i) in subparagraph (A)—

5 (I) in clause (ii), by striking “or”
6 at the end;

7 (II) in clause (iii), by striking the
8 semicolon at the end and inserting “,
9 including an emerging infectious mos-
10 quito-borne disease that presents a se-
11 rious public health threat; or”;

12 (III) by adding at the end the
13 following:

14 “(iv) a public health emergency due to
15 the incidence or prevalence of a mosquito-
16 borne disease that presents a serious pub-
17 lic health threat;”; and

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

20 “(D)(i) is located in a State that has re-
21 ceived a grant under subsection (a); or

22 “(ii) that demonstrates to the Secretary
23 that the control program is consistent with ex-
24 isting State mosquito control plans or policies,
25 or other applicable State preparedness plans.”;

1 (C) in paragraph (4)(C), by striking “that
2 extraordinary” and all that follows through the
3 period at the end and inserting the following:

4 “that—

5 “(i) extraordinary economic conditions
6 in the political subdivision or consortium of
7 political subdivisions involved justify the
8 waiver; or

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

13 “(I) the size or density of the po-
14 tentially impacted human population;

15 “(II) the size or density of a
16 mosquito population that requires
17 heightened control; or

18 “(III) the severity of the mos-
19 quito-borne disease, such that ex-
20 pected serious adverse health out-
21 comes for the human population jus-
22 tify the waiver.”; and

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

1 “(6) NUMBER OF GRANTS.—A political subdivi-
2 sion or a consortium of political subdivisions may
3 not receive more than one grant under paragraph
4 (1).”; and

5 (3) in subsection (f)—

6 (A) in paragraph (1) by striking “for fiscal
7 year 2003, and such sums as may be necessary
8 for each of fiscal years 2004 through 2007”
9 and inserting “for each of fiscal years 2019
10 through 2023”;

11 (B) in paragraph (2), by striking “the
12 Public Health Security and Bioterrorism Pre-
13 paredness and Response Act of 2002” and in-
14 serting “this Act and other medical and public
15 health preparedness and response laws”; and

16 (C) in paragraph (3)—

17 (i) in the paragraph heading, by strik-
18 ing “2004” and inserting “2019”; and

19 (ii) by striking “2004,” and inserting
20 “2019,”.

21 (b) EPIDEMIOLOGY-LABORATORY CAPACITY
22 GRANTS.—Section 2821 (42 U.S.C. 300hh–31) is amend-
23 ed—

1 (1) in subsection (a)(1), by inserting “, includ-
2 ing mosquito and other vector-borne diseases,” after
3 “infectious diseases”; and

4 (2) in subsection (b), by striking “2010 through
5 2013” and inserting “2019 through 2023”.

6 **TITLE VII—MISCELLANEOUS** 7 **PROVISIONS**

8 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

9 (a) **VETERANS AFFAIRS.**—Section 8117(g) of title
10 38, United States Code, is amended by striking “2014
11 through 2018” and inserting “2019 through 2023”.

12 (b) **VACCINE TRACKING AND DISTRIBUTION.**—Sec-
13 tion 319A(e) (42 U.S.C. 247d–1(e)) is amended by strik-
14 ing “2014 through 2018” and inserting “2019 through
15 2023”.

16 (c) **TEMPORARY REASSIGNMENT.**—Section 319(e)(8)
17 (42 U.S.C. 247d(e)(8)) is amended by striking “2018”
18 and inserting “2023”.

19 (d) **STRATEGIC INNOVATION PARTNER.**—Section
20 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is
21 amended by striking “2022” and inserting “2023”.

22 (e) **LIMITED ANTITRUST EXEMPTION.**—

23 (1) **IN GENERAL.**—Section 405 of the Pandemic
24 and All-Hazards Preparedness Act (Public Law
25 109–417; 42 U.S.C. 247d–6a note) is amended—

1 (A) in subsection (a)(1)(A)—

2 (i) by striking “Secretary of Health
3 and Human Services (referred to in this
4 subsection as the ‘Secretary’)” and insert-
5 ing “Secretary”;

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

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

12 (iv) by striking “of the Public Health
13 Service Act (42 U.S.C. 247d–6d)”;

14 (B) in subsection (b), by striking “12-
15 year” and inserting “17-year”;

16 (C) by redesignating such section 405 as
17 section 319L–1; and

18 (D) by transferring such section 319L–1,
19 as redesignated, to the Public Health Service
20 Act (42 U.S.C. 201 et seq.), to appear after
21 section 319L of such Act (42 U.S.C. 247d–7e).

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

1 (f) INAPPLICABILITY OF CERTAIN PROVISIONS.—
2 Subsection (e)(1) of section 319L (42 U.S.C. 247d—
3 7e(e)(1)) is amended—

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

6 “(A) NON-DISCLOSURE OF INFORMA-
7 TION.—

8 “(i) IN GENERAL.—Information de-
9 scribed in clause (ii) shall be deemed to be
10 information described in section 552(b)(3)
11 of title 5, United States Code.

12 “(ii) INFORMATION DESCRIBED.—The
13 information described in this clause is in-
14 formation relevant to programs of the De-
15 partment of Health and Human Services
16 that could compromise national security
17 and reveal significant and not otherwise
18 publicly known vulnerabilities of existing
19 medical or public health defenses against
20 chemical, biological, radiological, or nuclear
21 threats, and is comprised of—

22 “(I) specific technical data or sci-
23 entific information that is created or
24 obtained during the countermeasure
25 and product advanced research and

1 development carried out under sub-
2 section (c);

3 “(II) information pertaining to
4 the location security, personnel, and
5 research materials and methods of
6 high-containment laboratories con-
7 ducting research with select agents,
8 toxins, or other agents with a material
9 threat determination under section
10 319F–2(c)(2); or

11 “(III) security and vulnerability
12 assessments.”;

13 (2) by redesignating subparagraph (C) as sub-
14 paragraph (D);

15 (3) by inserting after subparagraph (B) the fol-
16 lowing:

17 “(C) REPORTING.—One year after the
18 date of enactment of the Pandemic and All-
19 Hazards Preparedness and Advancing Innova-
20 tion Act of 2018, and annually thereafter, the
21 Secretary shall report to the Committee on
22 Health, Education, Labor, and Pensions of the
23 Senate and the Committee on Energy and Com-
24 merce of the House of Representatives on the
25 number of instances in which the Secretary has

1 used the authority under this subsection to
2 withhold information from disclosure, as well as
3 the nature of any request under section 552 of
4 title 5, United States Code that was denied
5 using such authority.”; and

6 (4) in subparagraph (D), as so redesignated, by
7 striking “12” and inserting “17”.

8 **SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.**

9 Subsection (d) of section 319F–2 (42 U.S.C. 247d–
10 6b) is amended to read as follows:

11 “(d) DISCLOSURES.—No Federal agency may dis-
12 close under section 552 of title 5, United States Code any
13 information identifying the location at which materials in
14 the stockpile described in subsection (a) are stored, or
15 other information regarding the contents or deployment
16 capability of the stockpile that could compromise national
17 security.”.

18 **SEC. 703. CYBERSECURITY.**

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

21 (1) STRATEGY.—Not later than 18 months
22 after the date of enactment of this Act, the Sec-
23 retary of Health and Human Services (referred to in
24 this section as the “Secretary”) shall prepare and
25 submit to the relevant committees of Congress a

1 strategy for public health preparedness and response
2 to address cybersecurity threats (as defined in sec-
3 tion 102 of Cybersecurity Information Sharing Act
4 of 2015 (6 U.S.C. 1501)) that present a threat to
5 national health security. Such strategy shall in-
6 clude—

7 (A) identifying the duties, functions, and
8 preparedness goals for which the Secretary is
9 responsible in order to prepare for and respond
10 to such cybersecurity threats, including metrics
11 by which to measure success in meeting pre-
12 paredness goals;

13 (B) identifying gaps in public health capa-
14 bilities to achieve such preparedness goals; and

15 (C) strategies to address identified gaps
16 and strengthen public health emergency pre-
17 paredness and response capabilities to address
18 such cybersecurity threats.

19 (2) PROTECTION OF NATIONAL SECURITY.—

20 The Secretary shall make such strategy available to
21 the Committee on Health, Education, Labor, and
22 Pensions of the Senate, the Committee on Energy
23 and Commerce of the House of Representatives, and
24 other congressional committees of jurisdiction, in a
25 manner that does not compromise national security.

1 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
2 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
3 GENCIES.—Subparagraph (D) of section 2811(b)(4) (42
4 U.S.C. 300hh–10(b)(4)) is amended to read as follows:

5 “(D) POLICY COORDINATION AND STRA-
6 TEGIC DIRECTION.—Provide integrated policy
7 coordination and strategic direction, before,
8 during, and following public health emergencies,
9 with respect to all matters related to Federal
10 public health and medical preparedness and
11 execution and deployment of the Federal re-
12 sponse for public health emergencies and inci-
13 dents covered by the National Response Plan
14 described in section 504(a)(6) of the Homeland
15 Security Act of 2002 (6 U.S.C. 314(a)(6)), or
16 any successor plan; and such Federal responses
17 covered by the National Cybersecurity Incident
18 Response Plan developed under section 228(c)
19 of the Homeland Security Act of 2002 (6
20 U.S.C. 149(c)), including public health emer-
21 gencies or incidents related to cybersecurity
22 threats that present a threat to national health
23 security.”.

1 **SEC. 704. STRATEGY AND REPORT.**

2 Not later than 14 days after the date of the enact-
3 ment of this Act, the Secretary of Health and Human
4 Services, in coordination with the Assistant Secretary for
5 Preparedness and Response and the Assistant Secretary
6 for the Administration on Children and Families or other
7 appropriate office, and in collaboration with other depart-
8 ments, as appropriate, shall submit to the Committee on
9 Energy and Commerce of the House of Representatives,
10 the Committee on Health, Education, Labor, and Pen-
11 sions of the Senate, and other relevant congressional com-
12 mittees—

13 (1) a formal strategy, including interdepart-
14 mental actions and efforts to reunify children with
15 their parents or guardians, in all cases in which such
16 children have been separated from their parents or
17 guardians as a result of the initiative announced on
18 April 6, 2018, and due to prosecution under section
19 275(a) of the Immigration and Nationality Act (8
20 U.S.C. 1325(a)), if the parent or guardian chooses
21 such reunification and the child—

22 (A) was separated from a parent or guard-
23 ian and placed into a facility funded by the De-
24 partment of Health and Human Services;

1 (B) as of the date of the enactment of this
2 Act, remains in the care of the Department of
3 Health and Human Services; and

4 (C) can be safely reunited with such parent
5 or guardian; and

6 (2) a report on challenges and deficiencies re-
7 lated to the oversight of, and care for, unaccom-
8 panied alien children and appropriately reuniting
9 such children with their parents or guardians, and
10 the actions taken to address any challenges and defi-
11 ciencies related to unaccompanied alien children in
12 the custody of the Department of Health and
13 Human Services, including deficiencies identified
14 and publicly reported by Congress, the Government
15 Accountability Office, or the Inspectors General of
16 the Department of Health and Human Services or
17 other Federal departments.

18 **SEC. 705. TECHNICAL AMENDMENTS.**

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

21 (1) in paragraphs (1) and (5) of section 319F–
22 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
23 319F(h)” each place such term appears and insert-
24 ing “section 319F(e)”; and

1 (2) in section 319K(a) (42 U.S.C. 247d–7d(a)),
2 by striking “section 319F(h)(4)” and inserting “sec-
3 tion 319F(e)(4)”.

4 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
5 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

6 (1) in subparagraph (C), by striking “individ-
7 uals,” and inserting “individuals,”; and

8 (2) in subparagraph (F), by striking “make sat-
9 isfactory annual improvement and describe” and in-
10 serting “makes satisfactory annual improvement and
11 describes”.

12 (c) EMERGENCY USE INSTRUCTIONS.—Subpara-
13 graph (A) of section 564A(e)(2) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
15 amended by striking “subsection (a)(1)(C)(i)” and insert-
16 ing “subsection (a)(1)(C)”.

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

20 (1) in subparagraph (B), by inserting a comma
21 after “505”; and

22 (2) in subparagraph (C), by inserting “or sec-
23 tion 564A” before the period at the end.

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

4 (1) by striking “Nothing in” and inserting the
5 following:

6 “(A) IN GENERAL.—Nothing in”;

7 (2) by inserting “or directing” after “author-
8 izing”;

9 (3) by striking “disclose any” and inserting
10 “disclose—

11 “(i) any”;

12 (4) by striking the period and inserting “; or”;

13 and

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

15 “(ii) in the case of a drug develop-
16 ment tool that may be used to support the
17 development of a qualified countermeasure,
18 security countermeasure, or qualified pan-
19 demic or epidemic product, as defined in
20 sections 319F–1, 319F–2, and 319F–3,
21 respectively, of the Public Health Service
22 Act, any information that the Secretary
23 determines has a significant potential to
24 affect national security.

1 **TITLE I—OTC DRUG REVIEW**

2 **SEC. 1001. REGULATION OF CERTAIN NONPRESCRIPTION**
3 **DRUGS THAT ARE MARKETED WITHOUT AN**
4 **APPROVED DRUG APPLICATION.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended by inserting after sec-
7 tion 505F of such Act (21 U.S.C. 355g) the following:

8 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**
9 **DRUGS THAT ARE MARKETED WITHOUT AN**
10 **APPROVED DRUG APPLICATION.**

11 “(a) NONPRESCRIPTION DRUGS MARKETED WITH-
12 OUT AN APPROVED APPLICATION.—Nonprescription
13 drugs marketed without an approved drug application
14 under section 505, as of the date of the enactment of this
15 section, shall be treated in accordance with this sub-
16 section.

17 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
18 CATEGORY I DRUGS SUBJECT TO A TENTATIVE
19 FINAL MONOGRAPH.—A drug is deemed to be gen-
20 erally recognized as safe and effective under section
21 201(p)(1), not a new drug under section 201(p), and
22 not subject to section 503(b)(1), if—

23 “(A) the drug is—

24 “(i) in conformity with the require-
25 ments for nonprescription use of a final

1 monograph issued under part 330 of title
2 21, Code of Federal Regulations (except as
3 provided in paragraph (2)), the general re-
4 quirements for nonprescription drugs, and
5 conditions or requirements under sub-
6 sections (b), (c), and (k); and

7 “(ii) except as permitted by an order
8 issued under subsection (b) or, in the case
9 of a minor change in the drug, in con-
10 formity with an order issued under sub-
11 section (c), in a dosage form that, imme-
12 diately prior to the date of the enactment
13 of this section, has been used to a material
14 extent and for a material time under sec-
15 tion 201(p)(2); or

16 “(B) the drug is—

17 “(i) classified in category I for safety
18 and effectiveness under a tentative final
19 monograph that is the most recently appli-
20 cable proposal or determination issued
21 under part 330 of title 21, Code of Federal
22 Regulations;

23 “(ii) in conformity with the proposed
24 requirements for nonprescription use of
25 such tentative final monograph, any appli-

1 cable subsequent determination by the Sec-
2 retary, the general requirements for non-
3 prescription drugs, and conditions or re-
4 quirements under subsections (b), (c), and
5 (k); and

6 “(iii) except as permitted by an order
7 issued under subsection (b) or, in the case
8 of a minor change in the drug, in con-
9 formity with an order issued under sub-
10 section (c), in a dosage form that, imme-
11 diately prior to the date of the enactment
12 of this section, has been used to a material
13 extent and for a material time under sec-
14 tion 201(p)(2).

15 “(2) TREATMENT OF SUNSCREEN DRUGS.—

16 With respect to sunscreen drugs subject to this sec-
17 tion, the applicable requirements in terms of con-
18 formity with a final monograph, for purposes of
19 paragraph (1)(A)(i), shall be the requirements speci-
20 fied in part 352 of title 21, Code of Federal Regula-
21 tions, as published on May 21, 1999, beginning on
22 page 27687 of volume 64 of the Federal Register,
23 except that the applicable requirements governing ef-
24 fectiveness and labeling shall be those specified in

1 section 201.327 of title 21, Code of Federal Regula-
2 tions.

3 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-
4 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS
5 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE
6 NOTICE OF PROPOSED RULEMAKING.—A drug that
7 is not described in paragraph (1), (2), or (4) is not
8 required to be the subject of an application approved
9 under section 505, and is not subject to section
10 503(b)(1), if—

11 “(A) the drug is—

12 “(i) classified in category III for safe-
13 ty or effectiveness in the preamble of a
14 proposed rule establishing a tentative final
15 monograph that is the most recently appli-
16 cable proposal or determination for such
17 drug issued under part 330 of title 21,
18 Code of Federal Regulations;

19 “(ii) in conformity with—

20 “(I) the conditions of use, includ-
21 ing indication and dosage strength, if
22 any, described for such category III
23 drug in such preamble or in an appli-
24 cable subsequent proposed rule;

1 “(II) the proposed requirements
2 for drugs classified in such tentative
3 final monograph in category I in the
4 most recently proposed rule estab-
5 lishing requirements related to such
6 tentative final monograph and in any
7 final rule establishing requirements
8 that are applicable to the drug; and

9 “(III) the general requirements
10 for nonprescription drugs and condi-
11 tions or requirements under sub-
12 section (b) or (k); and

13 “(iii) in a dosage form that, imme-
14 diately prior to the date of the enactment
15 of this section, had been used to a material
16 extent and for a material time under sec-
17 tion 201(p)(2); or

18 “(B) the drug is—

19 “(i) classified in category I for safety
20 and effectiveness under a proposed mono-
21 graph or advance notice of proposed rule-
22 making that is the most recently applicable
23 proposal or determination for such drug
24 issued under part 330 of title 21, Code of
25 Federal Regulations;

1 “(ii) in conformity with the require-
2 ments for nonprescription use of such pro-
3 posed monograph or advance notice of pro-
4 posed rulemaking, any applicable subse-
5 quent determination by the Secretary, the
6 general requirements for nonprescription
7 drugs, and conditions or requirements
8 under subsection (b) or (k); and

9 “(iii) in a dosage form that, imme-
10 diately prior to the date of the enactment
11 of this section, has been used to a material
12 extent and for a material time under sec-
13 tion 201(p)(2).

14 “(4) CATEGORY II DRUGS DEEMED NEW
15 DRUGS.—A drug that is classified in category II for
16 safety or effectiveness under a tentative final mono-
17 graph or that is subject to a determination to be not
18 generally recognized as safe and effective in a pro-
19 posed rule that is the most recently applicable pro-
20 posal issued under part 330 of title 21, Code of Fed-
21 eral Regulations, shall be deemed to be a new drug
22 under section 201(p), misbranded under section
23 502(ee), and subject to the requirement for an ap-
24 proved new drug application under section 505 be-
25 ginning on the day that is 180 calendar days after

1 the date of the enactment of this section, unless, be-
2 fore such day, the Secretary determines that it is in
3 the interest of public health to extend the period
4 during which the drug may be marketed without
5 such an approved new drug application.

6 “(5) DRUGS NOT GRASE DEEMED NEW
7 DRUGS.—A drug that the Secretary has determined
8 not to be generally recognized as safe and effective
9 under section 201(p)(1) under a final determination
10 issued under part 330 of title 21, Code of Federal
11 Regulations, shall be deemed to be a new drug under
12 section 201(p), misbranded under section 502(ee),
13 and subject to the requirement for an approved new
14 drug application under section 505.

15 “(6) OTHER DRUGS DEEMED NEW DRUGS.—
16 Except as provided in subsection (m), a drug is
17 deemed to be a new drug under section 201(p) and
18 misbranded under section 502(ee) if the drug—

19 “(A) is not subject to section 503(b)(1);

20 and

21 “(B) is not described in paragraph (1),

22 (2), (3), (4), or (5), or subsection (b)(1)(B).

23 “(b) ADMINISTRATIVE ORDERS.—

24 “(1) IN GENERAL.—

1 “(A) DETERMINATION.—The Secretary
2 may, on the initiative of the Secretary or at the
3 request of one or more requestors, issue an ad-
4 ministrative order determining whether there
5 are conditions under which a specific drug, a
6 class of drugs, or a combination of drugs, is de-
7 termined to be—

8 “(i) not subject to section 503(b)(1);

9 and

10 “(ii) generally recognized as safe and
11 effective under section 201(p)(1).

12 “(B) EFFECT.—A drug or combination of
13 drugs shall be deemed to not require approval
14 under section 505 if such drug or combination
15 of drugs—

16 “(i) is determined by the Secretary to
17 meet the conditions specified in clauses (i)
18 and (ii) of subparagraph (A);

19 “(ii) is marketed in conformity with
20 an administrative order under this sub-
21 section;

22 “(iii) meets the general requirements
23 for nonprescription drugs; and

24 “(iv) meets the requirements under
25 subsections (c) and (k).

1 “(C) STANDARD.—The Secretary shall find
2 that a drug is not generally recognized as safe
3 and effective under section 201(p)(1) if—

4 “(i) the evidence shows that the drug
5 is not generally recognized as safe and ef-
6 fective under section 201(p)(1); or

7 “(ii) the evidence is inadequate to
8 show that the drug is generally recognized
9 as safe and effective under section
10 201(p)(1).

11 “(2) ADMINISTRATIVE ORDERS INITIATED BY
12 THE SECRETARY.—

13 “(A) IN GENERAL.—In issuing an adminis-
14 trative order under paragraph (1) upon the
15 Secretary’s initiative, the Secretary shall—

16 “(i) make reasonable efforts to notify
17 informally, not later than 2 business days
18 before the issuance of the proposed order,
19 the sponsors of drugs who have a listing in
20 effect under section 510(j) for the drugs or
21 combination of drugs that will be subject
22 to the administrative order;

23 “(ii) after any such reasonable efforts
24 of notification—

1 “(I) issue a proposed administra-
2 tive order by publishing it on the
3 website of the Food and Drug Admin-
4 istration and include in such order the
5 reasons for the issuance of such order;
6 and

7 “(II) publish a notice of avail-
8 ability of such proposed order in the
9 Federal Register;

10 “(iii) except as provided in subpara-
11 graph (B), provide for a public comment
12 period with respect to such proposed order
13 of not less than 45 calendar days; and

14 “(iv) if, after completion of the pro-
15 ceedings specified in clauses (i) through
16 (iii), the Secretary determines that it is ap-
17 propriate to issue a final administrative
18 order—

19 “(I) issue the final administrative
20 order, together with a detailed state-
21 ment of reasons, which order shall not
22 take effect until the time for request-
23 ing judicial review under paragraph
24 (3)(D)(ii) has expired;

1 “(II) publish a notice of such
2 final administrative order in the Fed-
3 eral Register;

4 “(III) afford requestors of drugs
5 that will be subject to such order the
6 opportunity for formal dispute resolu-
7 tion up to the level of the Director of
8 the Center for Drug Evaluation and
9 Research, which initially must be re-
10 quested within 45 calendar days of
11 the issuance of the order, and, for
12 subsequent levels of appeal, within 30
13 calendar days of the prior decision;
14 and

15 “(IV) except with respect to
16 drugs described in paragraph (3)(B),
17 upon completion of the formal dispute
18 resolution procedure, inform the per-
19 sons which sought such dispute reso-
20 lution of their right to request a hear-
21 ing.

22 “(B) EXCEPTIONS.—When issuing an ad-
23 ministrative order under paragraph (1) on the
24 Secretary’s initiative proposing to determine
25 that a drug described in subsection (a)(3) is not

1 generally recognized as safe and effective under
2 section 201(p)(1), the Secretary shall follow the
3 procedures in subparagraph (A), except that—

4 “(i) the proposed order shall include
5 notice of—

6 “(I) the general categories of
7 data the Secretary has determined
8 necessary to establish that the drug is
9 generally recognized as safe and effec-
10 tive under section 201(p)(1); and

11 “(II) the format for submissions
12 by interested persons;

13 “(ii) the Secretary shall provide for a
14 public comment period of no less than 180
15 calendar days with respect to such pro-
16 posed order, except when the Secretary de-
17 termines, for good cause, that a shorter pe-
18 riod is in the interest of public health; and

19 “(iii) any person who submits data in
20 such comment period shall include a cer-
21 tification that the person has submitted all
22 evidence created, obtained, or received by
23 that person that is both within the cat-
24 egories of data identified in the proposed
25 order and relevant to a determination as to

1 whether the drug is generally recognized as
2 safe and effective under section 201(p)(1).

3 “(3) HEARINGS; JUDICIAL REVIEW.—

4 “(A) IN GENERAL.—Only a person who
5 participated in each stage of formal dispute res-
6 olution under subclause (III) of paragraph
7 (2)(A)(iv) of an administrative order with re-
8 spect to a drug may request a hearing con-
9 cerning a final administrative order issued
10 under such paragraph with respect to such
11 drug. If a hearing is sought, such person must
12 submit a request for a hearing, which shall be
13 based solely on information in the administra-
14 tive record, to the Secretary not later than 30
15 calendar days after receiving notice of the final
16 decision of the formal dispute resolution proce-
17 dure.

18 “(B) NO HEARING REQUIRED WITH RE-
19 SPECT TO ORDERS RELATING TO CERTAIN
20 DRUGS.—

21 “(i) IN GENERAL.—The Secretary
22 shall not be required to provide notice and
23 an opportunity for a hearing pursuant to
24 paragraph (2)(A)(iv) if the final adminis-
25 trative order involved relates to a drug—

1 “(I) that is described in sub-
2 section (a)(3)(A); and

3 “(II) with respect to which no
4 human or non-human data studies rel-
5 evant to the safety or effectiveness of
6 such drug have been submitted to the
7 administrative record since the
8 issuance of the most recent tentative
9 final monograph relating to such
10 drug.

11 “(ii) HUMAN DATA STUDIES AND
12 NON-HUMAN DATA DEFINED.—In this sub-
13 paragraph:

14 “(I) The term ‘human data stud-
15 ies’ means clinical trials of safety or
16 effectiveness (including actual use
17 studies), pharmacokinetics studies, or
18 bioavailability studies.

19 “(II) The term ‘non-human data’
20 means data from testing other than
21 with human subjects which provides
22 information concerning safety or ef-
23 fectiveness.

24 “(C) HEARING PROCEDURES.—

1 “(i) DENIAL OF REQUEST FOR HEAR-
2 ING.—If the Secretary determines that in-
3 formation submitted in a request for a
4 hearing under subparagraph (A) with re-
5 spect to a final administrative order issued
6 under paragraph (2)(A)(iv), does not iden-
7 tify the existence of a genuine and sub-
8 stantial question of material fact, the Sec-
9 retary may deny such request. In making
10 such a determination, the Secretary may
11 consider only information and data that
12 are based on relevant and reliable scientific
13 principles and methodologies.

14 “(ii) SINGLE HEARING FOR MULTIPLE
15 RELATED REQUESTS.—If more than one
16 request for a hearing is submitted with re-
17 spect to the same administrative order
18 under subparagraph (A), the Secretary
19 may direct that a single hearing be con-
20 ducted in which all persons whose hearing
21 requests were granted may participate.

22 “(iii) PRESIDING OFFICER.—The pre-
23 siding officer of a hearing requested under
24 subparagraph (A) shall—

1 “(I) be designated by the Sec-
2 retary;

3 “(II) not be an employee of the
4 Center for Drug Evaluation and Re-
5 search; and

6 “(III) not have been previously
7 involved in the development of the ad-
8 ministrative order involved or pro-
9 ceedings relating to that administra-
10 tive order.

11 “(iv) RIGHTS OF PARTIES TO HEAR-
12 ING.—The parties to a hearing requested
13 under subparagraph (A) shall have the
14 right to present testimony, including testi-
15 mony of expert witnesses, and to cross-ex-
16 amine witnesses presented by other parties.
17 Where appropriate, the presiding officer
18 may require that cross-examination by par-
19 ties representing substantially the same in-
20 terests be consolidated to promote effi-
21 ciency and avoid duplication.

22 “(v) FINAL DECISION.—

23 “(I) At the conclusion of a hear-
24 ing requested under subparagraph
25 (A), the presiding officer of the hear-

1 ing shall issue a decision containing
2 findings of fact and conclusions of
3 law. The decision of the presiding offi-
4 cer shall be final.

5 “(II) The final decision may not
6 take effect until the period under sub-
7 paragraph (D)(ii) for submitting a re-
8 quest for judicial review of such deci-
9 sion expires.

10 “(D) JUDICIAL REVIEW OF FINAL ADMIN-
11 ISTRATIVE ORDER.—

12 “(i) IN GENERAL.—The procedures
13 described in section 505(h) shall apply
14 with respect to judicial review of final ad-
15 ministrative orders issued under this sub-
16 section in the same manner and to the
17 same extent as such section applies to an
18 order described in such section except that
19 the judicial review shall be taken by filing
20 in an appropriate district court of the
21 United States in lieu of the appellate
22 courts specified in such section.

23 “(ii) PERIOD TO SUBMIT A REQUEST
24 FOR JUDICIAL REVIEW.—A person eligible
25 to request a hearing under this paragraph

1 and seeking judicial review of a final ad-
2 ministrative order issued under this sub-
3 section shall file such request for judicial
4 review not later than 60 calendar days
5 after the latest of—

6 “(I) the date on which notice of
7 such order is published;

8 “(II) the date on which a hearing
9 with respect to such order is denied
10 under subparagraph (B) or (C)(i);

11 “(III) the date on which a final
12 decision is made following a hearing
13 under subparagraph (C)(v); or

14 “(IV) if no hearing is requested,
15 the date on which the time for re-
16 questing a hearing expires.

17 “(4) EXPEDITED PROCEDURE WITH RESPECT
18 TO ADMINISTRATIVE ORDERS INITIATED BY THE
19 SECRETARY.—

20 “(A) IMMINENT HAZARD TO THE PUBLIC
21 HEALTH.—

22 “(i) IN GENERAL.—In the case of a
23 determination by the Secretary that a
24 drug, class of drugs, or combination of
25 drugs subject to this section poses an im-

1 minent hazard to the public health, the
2 Secretary, after first making reasonable ef-
3 forts to notify, not later than 48 hours be-
4 fore issuance of such order under this sub-
5 paragraph, sponsors who have a listing in
6 effect under section 510(j) for such drug
7 or combination of drugs—

8 “(I) may issue an interim final
9 administrative order for such drug,
10 class of drugs, or combination of
11 drugs under paragraph (1), together
12 with a detailed statement of the rea-
13 sons for such order;

14 “(II) shall publish in the Federal
15 Register a notice of availability of any
16 such order; and

17 “(III) shall provide for a public
18 comment period of at least 45 cal-
19 endar days with respect to such in-
20 terim final order.

21 “(ii) NONDELEGATION.—The Sec-
22 retary may not delegate the authority to
23 issue an interim final administrative order
24 under this subparagraph.

25 “(B) SAFETY LABELING CHANGES.—

1 “(i) IN GENERAL.—In the case of a
2 determination by the Secretary that a
3 change in the labeling of a drug, class of
4 drugs, or combination of drugs subject to
5 this section is reasonably expected to miti-
6 gate a significant or unreasonable risk of
7 a serious adverse event associated with use
8 of the drug, the Secretary may—

9 “(I) make reasonable efforts to
10 notify informally, not later than 48
11 hours before the issuance of the in-
12 terim final order, the sponsors of
13 drugs who have a listing in effect
14 under section 510(j) for such drug or
15 combination of drugs;

16 “(II) after reasonable efforts of
17 notification, issue an interim final ad-
18 ministrative order in accordance with
19 paragraph (1) to require such change,
20 together with a detailed statement of
21 the reasons for such order;

22 “(III) publish in the Federal
23 Register a notice of availability of
24 such order; and

1 “(IV) provide for a public com-
2 ment period of at least 45 calendar
3 days with respect to such interim final
4 order.

5 “(ii) CONTENT OF ORDER.—An in-
6 terim final order issued under this sub-
7 paragraph with respect to the labeling of a
8 drug may provide for new warnings and
9 other information required for safe use of
10 the drug.

11 “(C) EFFECTIVE DATE.—An order under
12 subparagraph (A) or (B) shall take effect on a
13 date specified by the Secretary.

14 “(D) FINAL ORDER.—After the completion
15 of the proceedings in subparagraph (A) or (B),
16 the Secretary shall—

17 “(i) issue a final order in accordance
18 with paragraph (1);

19 “(ii) publish a notice of availability of
20 such final administrative order in the Fed-
21 eral Register; and

22 “(iii) afford sponsors of such drugs
23 that will be subject to such an order the
24 opportunity for formal dispute resolution
25 up to the level of the Director of the Cen-

1 ter for Drug Evaluation and Research,
2 which must initially be within 45 calendar
3 days of the issuance of the order, and for
4 subsequent levels of appeal, within 30 cal-
5 endar days of the prior decision.

6 “(E) HEARINGS.—A sponsor of a drug
7 subject to a final order issued under subpara-
8 graph (D) and that participated in each stage
9 of formal dispute resolution under clause (iii) of
10 such subparagraph may request a hearing on
11 such order. The provisions of subparagraphs
12 (A), (B), and (C) of paragraph (3), other than
13 paragraph (3)(C)(v)(II), shall apply with re-
14 spect to a hearing on such order in the same
15 manner and to the same extent as such provi-
16 sions apply with respect to a hearing on an ad-
17 ministrative order issued under paragraph
18 (2)(A)(iv).

19 “(F) TIMING.—

20 “(i) FINAL ORDER AND HEARING.—

21 The Secretary shall—

22 “(I) not later than 6 months
23 after the date on which the comment
24 period closes under subparagraph (A)

1 or (B), issue a final order in accord-
2 ance with paragraph (1); and

3 “(II) not later than 12 months
4 after the date on which such final
5 order is issued, complete any hearing
6 under subparagraph (E).

7 “(ii) DISPUTE RESOLUTION RE-
8 QUEST.—The Secretary shall specify in an
9 interim final order issued under subpara-
10 graph (A) or (B) such shorter periods for
11 requesting dispute resolution under sub-
12 paragraph (D)(iii) as are necessary to
13 meet the requirements of this subpara-
14 graph.

15 “(G) JUDICIAL REVIEW.—A final order
16 issued pursuant to subparagraph (F) shall be
17 subject to judicial review in accordance with
18 paragraph (3)(D).

19 “(5) ADMINISTRATIVE ORDER INITIATED AT
20 THE REQUEST OF A REQUESTOR.—

21 “(A) IN GENERAL.—In issuing an adminis-
22 trative order under paragraph (1) at the re-
23 quest of a requestor with respect to certain
24 drugs, classes of drugs, or combinations of
25 drugs—

1 “(i) the Secretary shall, after receiv-
2 ing a request under this subparagraph, de-
3 termine whether the request is sufficiently
4 complete and formatted to permit a sub-
5 stantive review;

6 “(ii) if the Secretary determines that
7 the request is sufficiently complete and for-
8 matted to permit a substantive review, the
9 Secretary shall—

10 “(I) file the request; and

11 “(II) initiate proceedings with re-
12 spect to issuing an administrative
13 order in accordance with paragraphs
14 (2) and (3); and

15 “(iii) except as provided in paragraph
16 (6), if the Secretary determines that a re-
17 quest does not meet the requirements for
18 filing or is not sufficiently complete and
19 formatted to permit a substantive review,
20 the requestor may demand that the request
21 be filed over protest, and the Secretary
22 shall initiate proceedings to review the re-
23 quest in accordance with paragraph (2)(A).

24 “(B) REQUEST TO INITIATE PRO-
25 CEEDINGS.—

1 “(i) IN GENERAL.—A requestor seek-
2 ing an administrative order under para-
3 graph (1) with respect to certain drugs,
4 classes of drugs, or combinations of drugs,
5 shall submit to the Secretary a request to
6 initiate proceedings for such order in the
7 form and manner as specified by the Sec-
8 retary. Such requestor may submit a re-
9 quest under this subparagraph for the
10 issuance of an administrative order—

11 “(I) determining whether a drug
12 is generally recognized as safe and ef-
13 fective under section 201(p)(1), ex-
14 empt from section 503(b)(1), and not
15 required to be the subject of an ap-
16 proved application under section 505;
17 or

18 “(II) determining whether a
19 change to a condition of use of a drug
20 is generally recognized as safe and ef-
21 fective under section 201(p)(1), ex-
22 empt from section 503(b)(1), and not
23 required to be the subject of an ap-
24 proved application under section 505,

1 if, absent such a changed condition of
2 use, such drug is—

3 “(aa) generally recognized
4 as safe and effective under sec-
5 tion 201(p)(1) in accordance with
6 subsection (a)(1), (a)(2), or an
7 order under this subsection; or

8 “(bb) subject to subsection
9 (a)(3), but only if such requestor
10 initiates such request in conjunc-
11 tion with a request for the Sec-
12 retary to determine whether such
13 drug is generally recognized as
14 safe and effective under section
15 201(p)(1), which is filed by the
16 Secretary under subparagraph
17 (A)(ii).

18 “(ii) EXCEPTION.—The Secretary is
19 not required to complete review of a re-
20 quest for a change described in clause
21 (i)(II) if the Secretary determines that
22 there is an inadequate basis to find the
23 drug is generally recognized as safe and ef-
24 fective under section 201(p)(1) under para-

1 graph (1) and issues a final order an-
2 nouncing that determination.

3 “(iii) WITHDRAWAL.—The requestor
4 may withdraw a request under this para-
5 graph, according to the procedures set
6 forth pursuant to subsection (d)(2)(B).
7 Notwithstanding any other provision of
8 this section, if such request is withdrawn,
9 the Secretary may cease proceedings under
10 this subparagraph.

11 “(C) EXCLUSIVITY.—

12 “(i) IN GENERAL.—A final adminis-
13 trative order issued in response to a re-
14 quest under this section shall have the ef-
15 fect of authorizing solely the order re-
16 questor (or the licensees, assignees, or suc-
17 cessors in interest of such requestor with
18 respect to the subject of such order), for a
19 period of 18 months following the effective
20 date of such final order and beginning on
21 the date the requestor may lawfully market
22 such drugs pursuant to the order, to mar-
23 ket drugs—

24 “(I) incorporating changes de-
25 scribed in clause (ii); and

1 “(II) subject to the limitations
2 under clause (iv).

3 “(ii) CHANGES DESCRIBED.—A
4 change described in this clause is a change
5 subject to an order specified in clause (i),
6 which—

7 “(I) provides for a drug to con-
8 tain an active ingredient (including
9 any ester or salt of the active ingre-
10 dient) not previously incorporated in a
11 drug described in clause (iii); or

12 “(II) provides for a change in the
13 conditions of use of a drug, for which
14 new human data studies conducted or
15 sponsored by the requestor (or for
16 which the requestor has an exclusive
17 right of reference) were essential to
18 the issuance of such order.

19 “(iii) DRUGS DESCRIBED.—The drugs
20 described in this clause are drugs—

21 “(I) specified in subsection
22 (a)(1), (a)(2), or (a)(3);

23 “(II) subject to a final order
24 issued under this section;

1 “(III) subject to a final sun-
2 screen order (as defined in section
3 586(2)(A)); or

4 “(IV) described in subsection
5 (m)(1), other than drugs subject to an
6 active enforcement action under chap-
7 ter III of this Act.

8 “(iv) LIMITATIONS ON EXCLU-
9 SIVITY.—

10 “(I) IN GENERAL.—Only one 18-
11 month period under this subpara-
12 graph shall be granted, under each
13 order described in clause (i), with re-
14 spect to changes (to the drug subject
15 to such order) which are either—

16 “(aa) changes described in
17 clause (ii)(I), relating to active
18 ingredients; or

19 “(bb) changes described in
20 clause (ii)(II), relating to condi-
21 tions of use.

22 “(II) NO EXCLUSIVITY AL-
23 LOWED.—No exclusivity shall apply to
24 changes to a drug which are—

1 “(aa) the subject of a Tier 2
2 OTC monograph order request
3 (as defined in section 744L);

4 “(bb) safety-related changes,
5 as defined by the Secretary, or
6 any other changes the Secretary
7 considers necessary to assure
8 safe use; or

9 “(cc) changes related to
10 methods of testing safety or effi-
11 cacy.

12 “(v) NEW HUMAN DATA STUDIES DE-
13 FINED.—In this subparagraph, the term
14 ‘new human data studies’ means clinical
15 trials of safety or effectiveness (including
16 actual use studies), pharmacokinetics stud-
17 ies, or bioavailability studies, the results of
18 which—

19 “(I) have not been relied on by
20 the Secretary to support—

21 “(aa) a proposed or final de-
22 termination that a drug described
23 in subclause (I), (II), or (III) of
24 clause (iii) is generally recognized

1 as safe and effective under sec-
2 tion 201(p)(1); or

3 “(bb) approval of a drug
4 that was approved under section
5 505; and

6 “(II) do not duplicate the results
7 of another study that was relied on by
8 the Secretary to support—

9 “(aa) a proposed or final de-
10 termination that a drug described
11 in subclause (I), (II), or (III) of
12 clause (iii) is generally recognized
13 as safe and effective under sec-
14 tion 201(p)(1); or

15 “(bb) approval of a drug
16 that was approved under section
17 505.

18 “(6) INFORMATION REGARDING SAFE NON-
19 PRESCRIPTION MARKETING AND USE AS CONDITION
20 FOR FILING A GENERALLY RECOGNIZED AS SAFE
21 AND EFFECTIVE REQUEST.—

22 “(A) IN GENERAL.—In response to a re-
23 quest under this section that a drug described
24 in subparagraph (B) be generally recognized as
25 safe and effective, the Secretary—

1 “(i) may file such request, if the re-
2 quest includes information specified under
3 subparagraph (C) with respect to safe non-
4 prescription marketing and use of such
5 drug; or

6 “(ii) if the request fails to include in-
7 formation specified under subparagraph
8 (C), shall refuse to file such request and
9 require that nonprescription marketing of
10 the drug be pursuant to a new drug appli-
11 cation as described in subparagraph (D).

12 “(B) DRUG DESCRIBED.—A drug de-
13 scribed in this subparagraph is a nonprescrip-
14 tion drug which contains an active ingredient
15 not previously incorporated in a drug—

16 “(i) specified in subsection (a)(1),
17 (a)(2), or (a)(3);

18 “(ii) subject to a final order under
19 this section; or

20 “(iii) subject to a final sunscreen
21 order (as defined in section 586(2)(A)).

22 “(C) INFORMATION DEMONSTRATING
23 PRIMA FACIE SAFE NONPRESCRIPTION MAR-
24 KETING AND USE.—Information specified in

1 this subparagraph, with respect to a request de-
2 scribed in subparagraph (A)(i), is—

3 “(i) information sufficient for a prima
4 facie demonstration that the drug subject
5 to such request has a verifiable history of
6 being marketed and safely used by con-
7 sumers in the United States as a non-
8 prescription drug under comparable condi-
9 tions of use;

10 “(ii) if the drug has not been pre-
11 viously marketed in the United States as a
12 nonprescription drug, information suffi-
13 cient for a prima facie demonstration that
14 the drug was marketed and safely used
15 under comparable conditions of marketing
16 and use in a country listed in section
17 802(b)(1)(A) or designated by the Sec-
18 retary in accordance with section
19 802(b)(1)(B)—

20 “(I) for such period as needed to
21 provide reasonable assurances con-
22 cerning the safe nonprescription use
23 of the drug; and

24 “(II) during such time was sub-
25 ject to sufficient monitoring by a reg-

1 ulatory body considered acceptable by
2 the Secretary for such monitoring
3 purposes, including for adverse events
4 associated with nonprescription use of
5 the drug; or

6 “(iii) if the Secretary determines that
7 information described in clause (i) or (ii) is
8 not needed to provide a prima facie dem-
9 onstration that the drug can be safely mar-
10 keted and used as a nonprescription drug,
11 such other information the Secretary deter-
12 mines is sufficient for such purposes.

13 “(D) MARKETING PURSUANT TO NEW
14 DRUG APPLICATION.—In the case of a request
15 described in subparagraph (A)(ii), the drug
16 subject to such request may be re-submitted for
17 filing only if—

18 “(i) the drug is marketed as a non-
19 prescription drug, under conditions of use
20 comparable to the conditions specified in
21 the request, for such period as the Sec-
22 retary determines appropriate (not to ex-
23 ceed 5 consecutive years) pursuant to an
24 application approved under section 505;
25 and

1 “(ii) during such period, 1,000,000
2 retail packages of the drug, or an equiva-
3 lent quantity as determined by the Sec-
4 retary, were distributed for retail sale, as
5 determined in such manner as the Sec-
6 retary finds appropriate.

7 “(E) RULE OF APPLICATION.—Except in
8 the case of a request involving a drug described
9 in section 586(9), as in effect on January 1,
10 2017, if the Secretary refuses to file a request
11 under this paragraph, the requestor may not
12 file such request over protest under paragraph
13 (5)(A)(iii).

14 “(7) PACKAGING.—An administrative order
15 issued under paragraph (2), (4)(A), or (5) may in-
16 clude requirements for the packaging of a drug to
17 encourage use in accordance with labeling. Such re-
18 quirements may include unit dose packaging, re-
19 quirements for products intended for use by pedi-
20 atric populations, requirements to reduce risk of
21 harm from unsupervised ingestion, and other appro-
22 priate requirements. This paragraph does not au-
23 thorize the Food and Drug Administration to re-
24 quire standards or testing procedures as described in
25 part 1700 of title 16, Code of Federal Regulations.

1 “(8) FINAL AND TENTATIVE FINAL MONO-
2 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
3 ADMINISTRATIVE ORDERS.—

4 “(A) IN GENERAL.—A final monograph or
5 tentative final monograph described in subpara-
6 graph (B) shall be deemed to be a final admin-
7 istrative order under this subsection and may
8 be amended, revoked, or otherwise modified in
9 accordance with the procedures of this sub-
10 section.

11 “(B) MONOGRAPHS DESCRIBED.—For pur-
12 poses of subparagraph (A), a final monograph
13 or tentative final monograph is described in this
14 subparagraph if it—

15 “(i) establishes conditions of use for a
16 drug described in paragraph (1) or (2) of
17 subsection (a); and

18 “(ii) represents the most recently pro-
19 mulgated version of such conditions, in-
20 cluding as modified, in whole or in part, by
21 any proposed or final rule.

22 “(C) DEEMED ORDERS INCLUDE HARMO-
23 NIZING TECHNICAL AMENDMENTS.—The
24 deemed establishment of a final administrative
25 order under subparagraph (A) shall be con-

1 strued to include any technical amendments to
2 such order as the Secretary determines nec-
3 essary to ensure that such order is appro-
4 priately harmonized, in terms of terminology or
5 cross-references, with the applicable provisions
6 of this Act (and regulations thereunder) and
7 any other orders issued under this section.

8 “(c) PROCEDURE FOR MINOR CHANGES.—

9 “(1) IN GENERAL.—Minor changes in the dos-
10 age form of a drug that is described in paragraph
11 (1) or (2) of subsection (a) or the subject of an
12 order issued under subsection (b) may be made by
13 a requestor without the issuance of an order under
14 subsection (b) if—

15 “(A) the requestor maintains such infor-
16 mation as is necessary to demonstrate that the
17 change—

18 “(i) will not affect the safety or effec-
19 tiveness of the drug; and

20 “(ii) will not materially affect the ex-
21 tent of absorption or other exposure to the
22 active ingredient in comparison to a suit-
23 able reference product; and

24 “(B) the change is in conformity with the
25 requirements of an applicable administrative

1 order issued by the Secretary under paragraph
2 (3).

3 “(2) ADDITIONAL INFORMATION.—

4 “(A) ACCESS TO RECORDS.—A sponsor
5 shall submit records requested by the Secretary
6 relating to such a minor change under section
7 704(a)(4), within 15 business days of receiving
8 such a request, or such longer period as the
9 Secretary may provide.

10 “(B) INSUFFICIENT INFORMATION.—If the
11 Secretary determines that the information con-
12 tained in such records is not sufficient to dem-
13 onstrate that the change does not affect the
14 safety or effectiveness of the drug or materially
15 affect the extent of absorption or other expo-
16 sure to the active ingredient, the Secretary—

17 “(i) may so inform the sponsor of the
18 drug in writing; and

19 “(ii) if the Secretary so informs the
20 sponsor, shall provide the sponsor of the
21 drug with a reasonable opportunity to pro-
22 vide additional information.

23 “(C) FAILURE TO SUBMIT SUFFICIENT IN-
24 FORMATION.—If the sponsor fails to provide
25 such additional information within a time pre-

1 scribed by the Secretary, or if the Secretary de-
2 termines that such additional information does
3 not demonstrate that the change does not—

4 “(i) affect the safety or effectiveness
5 of the drug; or

6 “(ii) materially affect the extent of
7 absorption or other exposure to the active
8 ingredient in comparison to a suitable ref-
9 erence product,

10 the drug as modified is a new drug under sec-
11 tion 201(p) and shall be deemed to be mis-
12 branded under section 502(ee).

13 “(3) DETERMINING WHETHER A CHANGE WILL
14 AFFECT SAFETY OR EFFECTIVENESS.—

15 “(A) IN GENERAL.—The Secretary shall
16 issue one or more administrative orders speci-
17 fying requirements for determining whether a
18 minor change made by a sponsor pursuant to
19 this subsection will affect the safety or effective-
20 ness of a drug or materially affect the extent of
21 absorption or other exposure to an active ingre-
22 dient in the drug in comparison to a suitable
23 reference product, together with guidance for
24 applying those orders to specific dosage forms.

1 “(B) STANDARD PRACTICES.—The orders
2 and guidance issued by the Secretary under
3 subparagraph (A) shall take into account rel-
4 evant public standards and standard practices
5 for evaluating the quality of drugs, and may
6 take into account the special needs of popu-
7 lations, including children.

8 “(d) CONFIDENTIALITY OF INFORMATION SUB-
9 MITTED TO THE SECRETARY.—

10 “(1) IN GENERAL.—Subject to paragraph (2),
11 any information, including reports of testing con-
12 ducted on the drug or drugs involved, that is sub-
13 mitted by a requestor in connection with proceedings
14 on an order under this section (including any minor
15 change under subsection (c)) and is a trade secret
16 or confidential information subject to section
17 552(b)(4) of title 5, United States Code, or section
18 1905 of title 18, United States Code, shall not be
19 disclosed to the public unless the requestor consents
20 to that disclosure.

21 “(2) PUBLIC AVAILABILITY.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraph (B), the Secretary shall—

24 “(i) make any information submitted
25 by a requestor in support of a request

1 under subsection (b)(5)(A) available to the
2 public not later than the date on which the
3 proposed order is issued; and

4 “(ii) make any information submitted
5 by any other person with respect to an
6 order requested (or initiated by the Sec-
7 retary) under subsection (b), available to
8 the public upon such submission.

9 “(B) LIMITATIONS ON PUBLIC AVAIL-
10 ABILITY.—Information described in subpara-
11 graph (A) shall not be made public if—

12 “(i) the information pertains to phar-
13 maceutical quality information, unless such
14 information is necessary to establish stand-
15 ards under which a drug is generally rec-
16 ognized as safe and effective under section
17 201(p)(1);

18 “(ii) the information is submitted in a
19 requestor-initiated request, but the re-
20 questor withdraws such request, in accord-
21 ance with withdrawal procedures estab-
22 lished by the Secretary, before the Sec-
23 retary issues the proposed order;

24 “(iii) the Secretary requests and ob-
25 tains the information under subsection (c)

1 and such information is not submitted in
2 relation to an order under subsection (b);

3 or

4 “(iv) the information is of the type
5 contained in raw datasets.

6 “(e) UPDATES TO DRUG LISTING INFORMATION.—

7 A sponsor who makes a change to a drug subject to this
8 section shall submit updated drug listing information for
9 the drug in accordance with section 510(j) within 30 cal-
10 endar days of the date when the drug is first commercially
11 marketed, except that a sponsor who was the order re-
12 questor with respect to an order subject to subsection
13 (b)(5)(C) (or a licensee, assignee, or successor in interest
14 of such requestor) shall submit updated drug listing infor-
15 mation on or before the date when the drug is first com-
16 mercially marketed.

17 “(f) APPROVALS UNDER SECTION 505.—The provi-
18 sions of this section shall not be construed to preclude a
19 person from seeking or maintaining the approval of an ap-
20 plication for a drug under sections 505(b)(1), 505(b)(2),
21 and 505(j). A determination under this section that a drug
22 is not subject to section 503(b)(1), is generally recognized
23 as safe and effective under section 201(p)(1), and is not
24 a new drug under section 201(p) shall constitute a finding
25 that the drug is safe and effective that may be relied upon

1 for purposes of an application under section 505(b)(2), so
2 that the applicant shall be required to submit for purposes
3 of such application only information needed to support any
4 modification of the drug that is not covered by such deter-
5 mination under this section.

6 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-
7 DERS.—The Secretary shall establish, maintain, update
8 (as determined necessary by the Secretary but no less fre-
9 quently than annually), and make publicly available, with
10 respect to orders issued under this section—

11 “(1) a repository of each final order and in-
12 terim final order in effect, including the complete
13 text of the order; and

14 “(2) a listing of all orders proposed and under
15 development under subsection (b)(2), including—

16 “(A) a brief description of each such order;
17 and

18 “(B) the Secretary’s expectations, if re-
19 sources permit, for issuance of proposed orders
20 over a 3-year period.

21 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-
22 QUESTORS.—The Secretary shall establish procedures
23 under which sponsors or requestors may meet with appro-
24 priate officials of the Food and Drug Administration to
25 obtain advice on the studies and other information nec-

1 essary to support submissions under this section and other
2 matters relevant to the regulation of nonprescription
3 drugs and the development of new nonprescription drugs
4 under this section.

5 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-
6 QUESTORS.—The Secretary shall establish procedures to
7 facilitate efficient participation by multiple sponsors or re-
8 questors in proceedings under this section, including provi-
9 sion for joint meetings with multiple sponsors or reques-
10 tors or with organizations nominated by sponsors or re-
11 questors to represent their interests in a proceeding.

12 “(j) ELECTRONIC FORMAT.—All submissions under
13 this section shall be in electronic format.

14 “(k) EFFECT ON EXISTING REGULATIONS GOV-
15 ERNING NONPRESCRIPTION DRUGS.—

16 “(1) REGULATIONS OF GENERAL APPLICA-
17 BILITY TO NONPRESCRIPTION DRUGS.—Except as
18 provided in this subsection, nothing in this section
19 supersedes regulations establishing general require-
20 ments for nonprescription drugs, including regula-
21 tions of general applicability contained in parts 201,
22 250, and 330 of title 21, Code of Federal Regula-
23 tions, or any successor regulations. The Secretary
24 shall establish or modify such regulations by means

1 of rulemaking in accordance with section 553 of title
2 5, United States Code.

3 “(2) REGULATIONS ESTABLISHING REQUIRE-
4 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

5 “(A) The provisions of section 310.545 of
6 title 21, Code of Federal Regulations, as in ef-
7 fect on the day before the date of the enact-
8 ment of this section, shall be deemed to be a
9 final order under subsection (b).

10 “(B) Regulations in effect on the day be-
11 fore the date of the enactment of this section,
12 establishing requirements for specific non-
13 prescription drugs marketed pursuant to this
14 section (including such requirements in parts
15 201 and 250 of title 21, Code of Federal Regu-
16 lations), shall be deemed to be final orders
17 under subsection (b), only as they apply to
18 drugs—

19 “(i) subject to paragraph (1), (2), (3),
20 or (4) of subsection (a); or

21 “(ii) otherwise subject to an order
22 under this section.

23 “(3) WITHDRAWAL OF REGULATIONS.—The
24 Secretary shall withdraw regulations establishing
25 final monographs and the procedures governing the

1 over-the-counter drug review under part 330 and
2 other relevant parts of title 21, Code of Federal
3 Regulations (as in effect on the day before the date
4 of the enactment of this section), or make technical
5 changes to such regulations to ensure conformity
6 with appropriate terminology and cross references.
7 Notwithstanding subchapter II of chapter 5 of title
8 5, United States Code, any such withdrawal or tech-
9 nical changes shall be made without public notice
10 and comment and shall be effective upon publication
11 through notice in the Federal Register (or upon such
12 date as specified in such notice).

13 “(1) GUIDANCE.—The Secretary shall issue guidance
14 that specifies—

15 “(1) the procedures and principles for formal
16 meetings between the Secretary and sponsors or re-
17 questors for drugs subject to this section;

18 “(2) the format and content of data submis-
19 sions to the Secretary under this section;

20 “(3) the format of electronic submissions to the
21 Secretary under this section;

22 “(4) consolidated proceedings for appeal and
23 the procedures for such proceedings where appro-
24 priate; and

1 “(5) for minor changes in drugs, recommenda-
2 tions on how to comply with the requirements in or-
3 ders issued under subsection (c)(3).

4 “(m) RULE OF CONSTRUCTION.—

5 “(1) IN GENERAL.—This section shall not af-
6 fect the treatment or status of a nonprescription
7 drug—

8 “(A) that is marketed without an applica-
9 tion approved under section 505 as of the date
10 of the enactment of this section;

11 “(B) that is not subject to an order issued
12 under this section; and

13 “(C) to which paragraphs (1), (2), (3), (4),
14 or (5) of subsection (a) do not apply.

15 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
16 FOUND TO BE SUBJECT TO TIME AND EXTENT RE-
17 QUIREMENTS.—

18 “(A) Notwithstanding subsection (a), a
19 drug described in subparagraph (B) may only
20 be lawfully marketed, without an application
21 approved under section 505, pursuant to an
22 order issued under this section.

23 “(B) A drug described in this subpara-
24 graph is a drug which, prior to the date of the
25 enactment of this section, the Secretary deter-

1 mined in a proposed or final rule to be ineligible
2 for review under the OTC drug review (as such
3 phrase ‘OTC drug review’ was used in section
4 330.14 of title 21, Code of Federal Regulations,
5 as in effect on the day before the date of the
6 enactment of this section).

7 “(3) PRESERVATION OF AUTHORITY.—

8 “(A) Nothing in paragraph (1) shall be
9 construed to preclude or limit the applicability
10 of any provision of this Act other than this sec-
11 tion.

12 “(B) Nothing in subsection (a) shall be
13 construed to prohibit the Secretary from issuing
14 an order under this section finding a drug to be
15 not generally recognized as safe and effective
16 under section 201(p)(1), as the Secretary deter-
17 mines appropriate.

18 “(n) INVESTIGATIONAL NEW DRUGS.—A drug is not
19 subject to this section if an exemption for investigational
20 use under section 505(i) is in effect for such drug.

21 “(o) INAPPLICABILITY OF PAPERWORK REDUCTION
22 ACT.—Chapter 35 of title 44, United States Code, shall
23 not apply to collections of information made under this
24 section.

1 “(p) INAPPLICABILITY OF NOTICE AND COMMENT
2 RULEMAKING AND OTHER REQUIREMENTS.—The re-
3 quirements of subsection (b) shall apply with respect to
4 orders issued under this section instead of the require-
5 ments of subchapter II of chapter 5 of title 5, United
6 States Code.

7 “(q) DEFINITIONS.—In this section:

8 “(1) The term ‘nonprescription drug’ refers to
9 a drug not subject to the requirements of section
10 503(b)(1).

11 “(2) The term ‘sponsor’ refers to any person
12 marketing, manufacturing, or processing a drug
13 that—

14 “(A) is listed pursuant to section 510(j);
15 and

16 “(B) is or will be subject to an administra-
17 tive order under this section of the Food and
18 Drug Administration.

19 “(3) The term ‘requestor’ refers to any person
20 or group of persons marketing, manufacturing, proc-
21 essing, or developing a drug.”.

22 (b) GAO STUDY.—Not later than 4 years after the
23 date of enactment of this Act, the Comptroller General
24 of the United States shall submit a study to the Com-
25 mittee on Energy and Commerce of the House of Rep-

1 representatives and the Committee on Health, Education,
2 Labor, and Pensions of the Senate addressing the effec-
3 tiveness and overall impact of exclusivity under section
4 505G of the Federal Food, Drug, and Cosmetic Act, as
5 added by subsection (a), and section 586C of such Act
6 (21 U.S.C. 360fff-3), including the impact of such exclu-
7 sivity on consumer access. Such study shall include—

8 (1) an analysis of the impact of exclusivity
9 under such section 505G for nonprescription drug
10 products, including—

11 (A) the number of nonprescription drug
12 products that were granted exclusivity and the
13 indication for which the nonprescription drug
14 products were determined to be generally recog-
15 nized as safe and effective;

16 (B) whether the exclusivity for such drug
17 products was granted for—

18 (i) a new active ingredient (including
19 any ester or salt of the active ingredient);

20 or

21 (ii) changes in the conditions of use of
22 a drug, for which new human data studies
23 conducted or sponsored by the requestor
24 were essential;

1 (C) whether, and to what extent, the exclu-
2 sivity impacted the requestor's or sponsor's de-
3 cision to develop the drug product;

4 (D) an analysis of the implementation of
5 the exclusivity provision in such section 505G,
6 including—

7 (i) the resources used by the Food
8 and Drug Administration;

9 (ii) the impact of such provision on
10 innovation, as well as research and devel-
11 opment in the nonprescription drug mar-
12 ket;

13 (iii) the impact of such provision on
14 competition in the nonprescription drug
15 market;

16 (iv) the impact of such provision on
17 consumer access to nonprescription drug
18 products;

19 (v) the impact of such provision on
20 the prices of nonprescription drug prod-
21 ucts; and

22 (vi) whether the administrative orders
23 initiated by requestors under such section
24 505G have been sufficient to encourage the
25 development of nonprescription drug prod-

1 ucts that would likely not be otherwise de-
2 veloped, or developed in as timely a man-
3 ner; and

4 (E) whether the administrative orders ini-
5 tiated by requestors under such section 505G
6 have been sufficient incentive to encourage in-
7 novation in the nonprescription drug market;
8 and

9 (2) an analysis of the impact of exclusivity
10 under such section 586C for sunscreen ingredients,
11 including—

12 (A) the number of sunscreen ingredients
13 that were granted exclusivity and the specific
14 ingredient that was determined to be generally
15 recognized as safe and effective;

16 (B) whether, and to what extent, the exclu-
17 sivity impacted the requestor's or sponsor's de-
18 cision to develop the sunscreen ingredient;

19 (C) whether, and to what extent, the sun-
20 screen ingredient granted exclusivity had pre-
21 viously been available outside of the United
22 States;

23 (D) an analysis of the implementation of
24 the exclusivity provision in such section 586C,
25 including—

- 1 (i) the resources used by the Food
2 and Drug Administration;
- 3 (ii) the impact of such provision on
4 innovation, as well as research and devel-
5 opment in the sunscreen market;
- 6 (iii) the impact of such provision on
7 competition in the sunscreen market;
- 8 (iv) the impact of such provision on
9 consumer access to sunscreen products;
- 10 (v) the impact of such provision on
11 the prices of sunscreen products; and
- 12 (vi) whether the administrative orders
13 initiated by requestors under such section
14 505G have been utilized by sunscreen in-
15 gredient sponsors and whether such proc-
16 ess has been sufficient to encourage the
17 development of sunscreen ingredients that
18 would likely not be otherwise developed, or
19 developed in as timely a manner; and
- 20 (E) whether the administrative orders ini-
21 tiated by requestors under such section 586C
22 have been sufficient incentive to encourage in-
23 novation in the sunscreen market.

1 (c) CONFORMING AMENDMENT.—Section 751(d)(1)
2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379r(d)(1)) is amended—

4 (1) in the matter preceding subparagraph (A)—

5 (A) by striking “final regulation promul-
6 gated” and inserting “final order under section
7 505G”; and

8 (B) by striking “and not misbranded”; and

9 (2) in subparagraph (A), by striking “regula-
10 tion in effect” and inserting “regulation or order in
11 effect”.

12 **SEC. 1002. MISBRANDING.**

13 Section 502 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 352) is amended by adding at the end the
15 following:

16 “(ee) If it is a nonprescription drug that is subject
17 to section 505G, is not the subject of an application ap-
18 proved under section 505, and does not comply with the
19 requirements under section 505G.

20 “(ff) If it is a drug and it was manufactured, pre-
21 pared, propagated, compounded, or processed in a facility
22 for which fees have not been paid as required by section
23 744M.”.

1 **SEC. 1003. DRUGS EXCLUDED FROM THE OVER-THE-**
2 **COUNTER DRUG REVIEW.**

3 (a) IN GENERAL.—Nothing in this Act (or the
4 amendments made by this Act) shall apply to any non-
5 prescription drug (as defined in section 505G(q) of the
6 Federal Food, Drug, and Cosmetic Act, as added by sec-
7 tion 1001 of this Act) which was excluded by the Food
8 and Drug Administration from the Over-the-Counter
9 Drug Review in accordance with the paragraph numbered
10 25 on page 9466 of volume 37 of the Federal Register,
11 published on May 11, 1972.

12 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to preclude or limit the applica-
14 bility of any other provision of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 301 et seq.).

16 **SEC. 1004. TREATMENT OF SUNSCREEN INNOVATION ACT.**

17 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
18 TIVE INGREDIENTS.—

19 (1) APPLICABILITY OF SECTION 505G FOR
20 PENDING SUBMISSIONS.—

21 (A) IN GENERAL.—A sponsor of a non-
22 prescription sunscreen active ingredient or com-
23 bination of nonprescription sunscreen active in-
24 gredients that, as of the date of enactment of
25 this Act, is subject to a proposed sunscreen
26 order under section 586C of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
2 may elect, by means of giving written notifica-
3 tion to the Secretary of Health and Human
4 Services within 180 calendar days of the enact-
5 ment of this Act, to transition into the review
6 of such ingredient or combination of ingredients
7 pursuant to the process set out in section 505G
8 of the Federal Food, Drug, and Cosmetic Act,
9 as added by section 1001 of this Act.

10 (B) ELECTION EXERCISED.—Upon receipt
11 by the Secretary of Health and Human Services
12 of a timely notification under subparagraph
13 (A)—

14 (i) the proposed sunscreen order in-
15 volved is deemed to be a request for an
16 order under subsection (b) of section 505G
17 of the Federal Food, Drug, and Cosmetic
18 Act, as added by section 1001 of this Act;
19 and

20 (ii) such order is deemed to have been
21 accepted for filing under subsection
22 (b)(6)(A)(i) of such section 505G.

23 (C) ELECTION NOT EXERCISED.—If a noti-
24 fication under subparagraph (A) is not received
25 by the Secretary of Health and Human Services

1 within 180 calendar days of the date of enact-
2 ment of this Act, the review of the proposed
3 sunscreen order described in subparagraph
4 (A)—

5 (i) shall continue under section 586C
6 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 360fff-3); and

8 (ii) shall not be eligible for review
9 under section 505G, added by section 1001
10 of this Act.

11 (2) DEFINITIONS.—In this subsection, the
12 terms “sponsor”, “nonprescription”, “sunscreen ac-
13 tive ingredient”, and “proposed sunscreen order”
14 have the meanings given to those terms in section
15 586 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360fff).

17 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

18 (1) FINAL SUNSCREEN ORDERS.—Paragraph
19 (3) of section 586C(e) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 360fff-3(e)) is amend-
21 ed to read as follows:

22 “(3) RELATIONSHIP TO ORDERS UNDER SEC-
23 TION 505G.—A final sunscreen order shall be deemed
24 to be a final order under section 505G.”.

1 (2) MEETINGS.—Paragraph (7) of section
2 586C(b) of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 360fff–3(b)) is amended—

4 (A) by striking “A sponsor may request”
5 and inserting the following:

6 “(A) IN GENERAL.—A sponsor may re-
7 quest”; and

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

9 “(B) CONFIDENTIAL MEETINGS.—A spon-
10 sor may request one or more confidential meet-
11 ings with respect to a proposed sunscreen order,
12 including a letter deemed to be a proposed sun-
13 screen order under paragraph (3), to discuss
14 matters relating to data requirements to sup-
15 port a general recognition of safety and effec-
16 tiveness involving confidential information and
17 public information related to such proposed
18 sunscreen order, as appropriate. The Secretary
19 shall convene a confidential meeting with such
20 sponsor in a reasonable time period. If a spon-
21 sor requests more than one confidential meeting
22 for the same proposed sunscreen order, the Sec-
23 retary may refuse to grant an additional con-
24 fidential meeting request if the Secretary deter-
25 mines that such additional confidential meeting

1 is not reasonably necessary for the sponsor to
2 advance its proposed sunscreen order, or if the
3 request for a confidential meeting fails to in-
4 clude sufficient information upon which to base
5 a substantive discussion. The Secretary shall
6 publish a post-meeting summary of each con-
7 fidential meeting under this subparagraph that
8 does not disclose confidential commercial infor-
9 mation or trade secrets. This subparagraph
10 does not authorize the disclosure of confidential
11 commercial information or trade secrets subject
12 to 552(b)(4) of title 5, United States Code, or
13 section 1905 of title 18, United States Code.”.

14 (3) EXCLUSIVITY.—Section 586C of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 360fff-3) is amended by adding at the end the fol-
17 lowing:

18 “(f) EXCLUSIVITY.—

19 “(1) IN GENERAL.—A final sunscreen order
20 shall have the effect of authorizing solely the order
21 requestor (or the licensees, assignees, or successors
22 in interest of such requestor with respect to the sub-
23 ject of such request and listed under paragraph (5))
24 for a period of 18 months, to market a sunscreen in-
25 gredient under this section incorporating changes

1 described in paragraph (2) subject to the limitations
2 under paragraph (4), beginning on the date the re-
3 questor (or any licensees, assignees, or successors in
4 interest of such requestor with respect to the subject
5 of such request and listed under paragraph (5)) may
6 lawfully market such sunscreen ingredient pursuant
7 to the order.

8 “(2) CHANGES DESCRIBED.—A change de-
9 scribed in this paragraph is a change subject to an
10 order specified in paragraph (1) that permits a sun-
11 screen to contain an active sunscreen ingredient not
12 previously incorporated in a marketed sunscreen list-
13 ed in paragraph (3).

14 “(3) MARKETED SUNSCREEN.—The marketed
15 sunscreen ingredients described in this paragraph
16 are sunscreen ingredients—

17 “(A) marketed in accordance with a final
18 monograph for sunscreen drug products set
19 forth at part 352 of title 21, Code of Federal
20 Regulations (as published at 64 Fed. Reg.
21 27687); or

22 “(B) marketed in accordance with a final
23 order issued under this section.

1 “(4) LIMITATIONS ON EXCLUSIVITY.—Only one
2 18-month period may be granted per ingredient
3 under paragraph (1).

4 “(5) LISTING OF LICENSEES, ASSIGNEES, OR
5 SUCCESSORS IN INTEREST.—Requestors shall submit
6 to the Secretary at the time when a drug subject to
7 such request is introduced or delivered for introduc-
8 tion into interstate commerce, a list of licensees, as-
9 signees, or successors in interest under paragraph
10 (1).”.

11 (4) SUNSET PROVISION.—Subchapter I of chap-
12 ter V of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 360fff et seq.) is amended by adding at
14 the end the following:

15 **“SEC. 586H. SUNSET.**

16 “‘This subchapter shall cease to be effective at the end
17 of fiscal year 2022.’”.

18 (5) TREATMENT OF FINAL SUNSCREEN
19 ORDER.—The Federal Food, Drug, and Cosmetic
20 Act is amended by striking section 586E of such Act
21 (21 U.S.C. 360fff–5).

22 (c) TREATMENT OF AUTHORITY REGARDING FINAL-
23 IZATION OF SUNSCREEN MONOGRAPH.—

24 (1) IN GENERAL.—

1 (A) REVISION OF FINAL SUNSCREEN
2 ORDER.—Not later than November 26, 2019,
3 the Secretary of Health and Human Services
4 (referred to in this subsection as the “Sec-
5 retary”) shall amend and revise the final ad-
6 ministrative order concerning nonprescription
7 sunscreen (referred to in this subsection as the
8 “sunscreen order”) for which the content, prior
9 to the date of enactment of this Act, was rep-
10 resented by the final monograph for sunscreen
11 drug products set forth in part 352 of title 21,
12 Code of Federal Regulations (as in effect on
13 May 21, 1999).

14 (B) ISSUANCE OF REVISED SUNSCREEN
15 ORDER; EFFECTIVE DATE.—A revised sunscreen
16 order described in subparagraph (A) shall be—

17 (i) issued in accordance with the pro-
18 cedures described in section 505G(c)(2) of
19 the Federal Food, Drug, and Cosmetic
20 Act;

21 (ii) issued in proposed form not later
22 than May 28, 2019;

23 (iii) effective not later than November
24 26, 2020; and

1 (iv) issued by the Secretary at least 1
2 year prior to the effective date of the re-
3 vised order.

4 (2) REPORTS.—If a revised sunscreen order
5 issued under paragraph (1) does not include provi-
6 sions related to the effectiveness of various sun pro-
7 tection factor levels, and does not address all dosage
8 forms known to the Secretary to be used in sun-
9 screens marketed in the United States without a
10 new drug application approved under section 505 of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355), the Secretary shall submit a report to
13 the Committee on Energy and Commerce of the
14 House of Representatives and the Committee on
15 Health, Education, Labor, and Pensions of the Sen-
16 ate on the rationale for omission of such provisions
17 from such order, and a plan and timeline to compile
18 any information necessary to address such provisions
19 through such order.

20 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-
21 TENT APPLICATIONS.—

22 (1) IN GENERAL.—Any application described in
23 section 586F of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360fff-6) that was submitted
25 to the Secretary pursuant to section 330.14 of title

1 21, Code of Federal Regulations, as such provisions
2 were in effect immediately prior to the date of enact-
3 ment date of this Act, shall be extinguished as of
4 such date of enactment, subject to paragraph (2).

5 (2) ORDER REQUEST.—Nothing in paragraph
6 (1) precludes the submission of an order request
7 under section 505G(b) of the Federal Food, Drug,
8 and Cosmetic Act, as added by section 1001 of this
9 Act, with respect to a drug that was the subject of
10 an application extinguished under paragraph (1).

11 **SEC. 1005. ANNUAL UPDATE TO CONGRESS ON APPRO-**
12 **RIATE PEDIATRIC INDICATION FOR CER-**
13 **TAIN OTC COUGH AND COLD DRUGS.**

14 (a) IN GENERAL.—Subject to subsection (c), the Sec-
15 retary of Health and Human Services shall, beginning not
16 later than 1 year after the date of enactment of this Act,
17 annually submit to the Committee on Energy and Com-
18 merce of the House of Representatives and the Committee
19 on Health, Education, Labor, and Pensions of the Senate
20 a letter describing the progress of the Food and Drug Ad-
21 ministration—

22 (1) in evaluating the cough and cold monograph
23 described in subsection (b) with respect to children
24 under age 6; and

1 (2) as appropriate, revising such cough and cold
2 monograph to address such children through the
3 order process under section 505G(b) of the Federal
4 Food, Drug, and Cosmetic Act, as added by section
5 1001 of this Act.

6 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

7 The cough and cold monograph described in this sub-
8 section consists of the conditions under which nonprescrip-
9 tion drugs containing antitussive, expectorant, nasal de-
10 congestant, or antihistamine active ingredients (or com-
11 binations thereof) are generally recognized as safe and ef-
12 fective, as specified in part 341 of title 21, Code of Federal
13 Regulations (as in effect immediately prior to the date of
14 enactment of this Act), and included in an order deemed
15 to be established under section 505G(b) of the Federal
16 Food, Drug, and Cosmetic Act, as added by section 1001
17 of this Act.

18 (c) DURATION OF AUTHORITY.—The requirement
19 under subsection (a) shall terminate as of the date of a
20 letter submitted by the Secretary of Health and Human
21 Services pursuant to such subsection in which the Sec-
22 retary indicates that the Food and Drug Administration
23 has completed its evaluation and revised, in a final order,
24 as applicable, the cough and cold monograph as described
25 in subsection (a)(2).

1 **SEC. 1006. TECHNICAL CORRECTIONS.**

2 (a) IMPORTS AND EXPORTS.—Section
3 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking
5 “subparagraph” each place such term appears and insert-
6 ing “paragraph”.

7 (b) FDA REAUTHORIZATION ACT OF 2017.—

8 (1) IN GENERAL.—Section 905(b)(4) of the
9 FDA Reauthorization Act of 2017 (Public Law 115–
10 52) is amended by striking “Section 744H(e)(2)(B)”
11 and inserting “Section 744H(f)(2)(B)”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by paragraph (1) shall take effect as of the enact-
14 ment of the FDA Reauthorization Act of 2017
15 (Public Law 115–52).

16 **TITLE II—USER FEES**

17 **SEC. 2001. SHORT TITLE; FINDING.**

18 (a) SHORT TITLE.—This title may be cited as the
19 “Over-the-Counter Monograph User Fee Act of 2018”.

20 (b) FINDING.—The Congress finds that the fees au-
21 thorized by the amendments made in this title will be dedi-
22 cated to OTC monograph drug activities, as set forth in
23 the goals identified for purposes of part 10 of subchapter
24 C of chapter VII of the Federal Food, Drug, and Cosmetic
25 Act, in the letters from the Secretary of Health and
26 Human Services to the Chairman of the Committee on

1 Health, Education, Labor, and Pensions of the Senate and
2 the Chairman of the Committee on Energy and Commerce
3 of the House of Representatives, as set forth in the Con-
4 gressional Record.

5 **SEC. 2002. FEES RELATING TO OVER-THE-COUNTER DRUGS.**

6 Subchapter C of chapter VII of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is
8 amended by inserting after part 9 the following:

9 **“PART 10—FEES RELATING TO OVER-THE-**
10 **COUNTER DRUGS**

11 **“SEC. 744L. DEFINITIONS.**

12 “In this part:

13 “(1) The term ‘affiliate’ means a business enti-
14 ty that has a relationship with a second business en-
15 tity if, directly or indirectly—

16 “(A) one business entity controls, or has
17 the power to control, the other business entity;
18 or

19 “(B) a third party controls, or has power
20 to control, both of the business entities.

21 “(2) The term ‘contract manufacturing organi-
22 zation facility’ means an OTC monograph drug facil-
23 ity where neither the owner of such manufacturing
24 facility nor any affiliate of such owner or facility
25 sells the OTC monograph drug produced at such fa-

1 cility directly to wholesalers, retailers, or consumers
2 in the United States.

3 “(3) The term ‘costs of resources allocated for
4 OTC monograph drug activities’ means the expenses
5 in connection with OTC monograph drug activities
6 for—

7 “(A) officers and employees of the Food
8 and Drug Administration, contractors of the
9 Food and Drug Administration, advisory com-
10 mittees, and costs related to such officers, em-
11 ployees, and committees and costs related to
12 contracts with such contractors;

13 “(B) management of information, and the
14 acquisition, maintenance, and repair of com-
15 puter resources;

16 “(C) leasing, maintenance, renovation, and
17 repair of facilities and acquisition, maintenance,
18 and repair of fixtures, furniture, scientific
19 equipment, and other necessary materials and
20 supplies; and

21 “(D) collecting fees under section 744M
22 and accounting for resources allocated for OTC
23 monograph drug activities.

24 “(4) The term ‘FDA establishment identifier’ is
25 the unique number automatically generated by Food

1 and Drug Administration’s Field Accomplishments
2 and Compliance Tracking System (FACTS) (or any
3 successor system).

4 “(5) The term ‘OTC monograph drug’ means a
5 nonprescription drug without an approved new drug
6 application which is governed by the provisions of
7 section 505G.

8 “(6) The term ‘OTC monograph drug activities’
9 means activities of the Secretary associated with
10 OTC monograph drugs and inspection of facilities
11 associated with such products, including the fol-
12 lowing activities:

13 “(A) The activities necessary for review
14 and evaluation of OTC monographs and OTC
15 monograph order requests, including—

16 “(i) orders proposing or finalizing ap-
17 plicable conditions of use for OTC mono-
18 graph drugs;

19 “(ii) orders affecting status regarding
20 general recognition of safety and effective-
21 ness of an OTC monograph ingredient or
22 combination of ingredients under specified
23 conditions of use;

1 “(iii) all OTC monograph drug devel-
2 opment and review activities, including
3 intra-agency collaboration;

4 “(iv) regulation and policy develop-
5 ment activities related to OTC monograph
6 drugs;

7 “(v) development of product standards
8 for products subject to review and evalua-
9 tion;

10 “(vi) meetings referred to in section
11 505G(i);

12 “(vii) review of labeling prior to
13 issuance of orders related to OTC mono-
14 graph drugs or conditions of use; and

15 “(viii) regulatory science activities re-
16 lated to OTC monograph drugs.

17 “(B) Inspections related to OTC mono-
18 graph drugs.

19 “(C) Monitoring of clinical and other re-
20 search conducted in connection with OTC
21 monograph drugs.

22 “(D) Safety activities with respect to OTC
23 monograph drugs, including—

1 “(i) collecting, developing, and review-
2 ing safety information on OTC monograph
3 drugs, including adverse event reports;

4 “(ii) developing and using improved
5 adverse event data-collection systems, in-
6 cluding information technology systems;
7 and

8 “(iii) developing and using improved
9 analytical tools to assess potential safety
10 risks, including access to external data-
11 bases.

12 “(E) Other activities necessary for imple-
13 mentation of section 505G.

14 “(7) The term ‘OTC monograph order request’
15 means a request for an order submitted under sec-
16 tion 505G(b)(5).

17 “(8) The term ‘Tier 1 OTC monograph order
18 request’ means any OTC monograph order request
19 not determined to be a Tier 2 OTC monograph
20 order request.

21 “(9)(A) The term ‘Tier 2 OTC monograph
22 order request’ means, subject to subparagraph (B),
23 an OTC monograph order request for—

1 “(i) the reordering of existing information
2 in the drug facts label of an OTC monograph
3 drug;

4 “(ii) the addition of information to the
5 other information section of the drug facts label
6 of an OTC monograph drug, as limited by sec-
7 tion 201.66(c)(7) of title 21, Code of Federal
8 Regulations (or any successor regulations);

9 “(iii) modification to the directions for use
10 section of the drug facts label of an OTC mono-
11 graph drug, if such changes conform to changes
12 made pursuant to section 505G(c)(3)(A);

13 “(iv) the standardization of the concentra-
14 tion or dose of a specific finalized ingredient
15 within a particular finalized monograph;

16 “(v) a change to ingredient nomenclature
17 to align with nomenclature of a standards-set-
18 ting organization; or

19 “(vi) addition of an interchangeable term
20 in accordance with section 330.1 of title 21,
21 Code of Federal Regulations (or any successor
22 regulations).

23 “(B) The Secretary may, based on program im-
24 plementation experience or other factors found ap-
25 propriate by the Secretary, characterize any OTC

1 monograph order request as a Tier 2 OTC mono-
2 graph order request (including recharacterizing a re-
3 quest from Tier 1 to Tier 2) and publish such deter-
4 mination in a proposed order issued pursuant to sec-
5 tion 505G.

6 “(10)(A) The term ‘OTC monograph drug facil-
7 ity’ means a foreign or domestic business or other
8 entity that—

9 “(i) is—

10 “(I) under one management, either di-
11 rect or indirect; and

12 “(II) at one geographic location or ad-
13 dress engaged in manufacturing or proc-
14 essing the finished dosage form of an OTC
15 monograph drug;

16 “(ii) includes a finished dosage form man-
17 ufacturer facility in a contractual relationship
18 with the sponsor of one or more OTC mono-
19 graph drugs to manufacture or process such
20 drugs; and

21 “(iii) does not include a business or other
22 entity whose only manufacturing or processing
23 activities are one or more of the following: pro-
24 duction of clinical research supplies, testing, or
25 placement of outer packaging on packages con-

1 taining multiple products, for such purposes as
2 creating multipacks, when each monograph
3 drug product contained within the overpack-
4 aging is already in a final packaged form prior
5 to placement in the outer overpackaging.

6 “(B) For purposes of subparagraph (A)(i)(II),
7 separate buildings or locations within close proximity
8 are considered to be at one geographic location or
9 address if the activities conducted in such buildings
10 or locations are—

11 “(i) closely related to the same business
12 enterprise;

13 “(ii) under the supervision of the same
14 local management; and

15 “(iii) under a single FDA establishment
16 identifier and capable of being inspected by the
17 Food and Drug Administration during a single
18 inspection.

19 “(C) If a business or other entity would meet
20 criteria specified in subparagraph (A), but for being
21 under multiple management, the business or other
22 entity is deemed to constitute multiple facilities, one
23 per management entity, for purposes of this para-
24 graph.

1 “(11) The term ‘OTC monograph drug meet-
2 ing’ means any meeting regarding the content of a
3 proposed OTC monograph order request.

4 “(12) The term ‘person’ includes an affiliate of
5 a person.

6 “(13) The terms ‘requestor’ and ‘sponsor’ have
7 the meanings given such terms in section 505G.

8 **“SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONO-**
9 **GRAPH FEES.**

10 “(a) TYPES OF FEES.—Beginning with fiscal year
11 2019, the Secretary shall assess and collect fees in accord-
12 ance with this section as follows:

13 “(1) FACILITY FEE.—

14 “(A) IN GENERAL.—Each person that
15 owns a facility identified as an OTC monograph
16 drug facility on December 31 of the fiscal year
17 or at any time during the preceding 12-month
18 period shall be assessed an annual fee for each
19 such facility as determined under subsection
20 (c).

21 “(B) EXCEPTIONS.—

22 “(i) A fee shall not be assessed under
23 subparagraph (A) if the identified OTC
24 monograph drug facility—

1 “(I) has ceased all activities re-
2 lated to OTC monograph drugs prior
3 to January 31, 2019, for the first pro-
4 gram year, and December 31 of the
5 fiscal year for subsequent fiscal years;
6 and

7 “(II) has updated its registration
8 to reflect such change under the re-
9 quirements for drug establishment
10 registration set forth in section 510.

11 “(ii) The amount of the fee for a con-
12 tract manufacturing organization facility
13 shall be equal to two-thirds of the amount
14 of the fee for an OTC monograph drug fa-
15 cility that is not a contract manufacturing
16 organization facility.

17 “(C) AMOUNT.—The amount of fees estab-
18 lished under subparagraph (A) shall be estab-
19 lished under subsection (c).

20 “(D) DUE DATE.—

21 “(i) FOR FIRST PROGRAM YEAR.—For
22 fiscal year 2019, the facility fees required
23 under subparagraph (A) shall be due 45
24 calendar days after publication of the Fed-

1 eral Register notice provided for under
2 subsection (c)(4)(A).

3 “(ii) SUBSEQUENT FISCAL YEARS.—
4 For each fiscal year after fiscal year 2019,
5 the facility fees required under subpara-
6 graph (A) shall be due on the later of—

7 “(I) the first business day of
8 June of such year; or

9 “(II) the first business day after
10 the enactment of an appropriations
11 Act providing for the collection and
12 obligation of fees under this section
13 for such year.

14 “(2) OTC MONOGRAPH ORDER REQUEST
15 FEE.—

16 “(A) IN GENERAL.—Each person that sub-
17 mits an OTC monograph order request shall be
18 subject to a fee for an OTC monograph order
19 request. The amount of such fee shall be—

20 “(i) for a Tier 1 OTC monograph
21 order request, \$500,000, adjusted for in-
22 flation for the fiscal year (as determined
23 under subsection (c)(1)(B)); and

24 “(ii) for a Tier 2 OTC monograph
25 order request, \$100,000 adjusted for infla-

1 tion for the fiscal year (as determined
2 under subsection (c)(1)(B)).

3 “(B) DUE DATE.—The OTC monograph
4 order request fees required under subparagraph
5 (A) shall be due on the date of submission of
6 the OTC monograph order request.

7 “(C) EXCEPTION FOR CERTAIN SAFETY
8 CHANGES.—A person who is named as the re-
9 questor in an OTC monograph order shall not
10 be subject to a fee under subparagraph (A) if
11 the Secretary finds that the OTC monograph
12 order request seeks to change the drug facts la-
13 beling of an OTC monograph drug in a way
14 that would add to or strengthen—

15 “(i) a contraindication, warning, or
16 precaution;

17 “(ii) a statement about risk associated
18 with misuse or abuse; or

19 “(iii) an instruction about dosage and
20 administration that is intended to increase
21 the safe use of the OTC monograph drug.

22 “(D) REFUND OF FEE IF ORDER REQUEST
23 IS RECATEGORIZED AS A TIER 2 OTC MONO-
24 GRAPH ORDER REQUEST.—If the Secretary de-
25 termines that an OTC monograph request ini-

1 tially characterized as Tier 1 shall be re-charac-
2 terized as a Tier 2 OTC monograph order re-
3 quest, and the requestor has paid a Tier 1 fee
4 in accordance with subparagraph (A)(i), the
5 Secretary shall refund the requestor the dif-
6 ference between the Tier 1 and Tier 2 fees de-
7 termined under subparagraphs (A)(i) and
8 (A)(ii), respectively.

9 “(E) REFUND OF FEE IF ORDER REQUEST
10 REFUSED FOR FILING OR WITHDRAWN BEFORE
11 FILING.—The Secretary shall refund 75 percent
12 of the fee paid under subparagraph (B) for any
13 order request which is refused for filing or was
14 withdrawn before being accepted or refused for
15 filing.

16 “(F) FEES FOR ORDER REQUESTS PRE-
17 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
18 BEFORE FILING.—An OTC monograph order
19 request that was submitted but was refused for
20 filing, or was withdrawn before being accepted
21 or refused for filing, shall be subject to the full
22 fee under subparagraph (A) upon being resub-
23 mitted or filed over protest.

24 “(G) REFUND OF FEE IF ORDER REQUEST
25 WITHDRAWN.—If an order request is withdrawn

1 after the order request was filed, the Secretary
2 may refund the fee or a portion of the fee if no
3 substantial work was performed on the order
4 request after the application was filed. The Sec-
5 retary shall have the sole discretion to refund a
6 fee or a portion of the fee under this subpara-
7 graph. A determination by the Secretary con-
8 cerning a refund under this subparagraph shall
9 not be reviewable.

10 “(3) REFUNDS.—

11 “(A) IN GENERAL.—Other than refunds
12 provided pursuant to any of subparagraphs (D)
13 through (G) of paragraph (2), the Secretary
14 shall not refund any fee paid under paragraph
15 (1) except as provided in subparagraph (B).

16 “(B) DISPUTES CONCERNING FEES.—To
17 qualify for the return of a fee claimed to have
18 been paid in error under paragraph (1) or (2),
19 a person shall submit to the Secretary a written
20 request justifying such return within 180 cal-
21 endar days after such fee was paid.

22 “(4) NOTICE.—Within the timeframe specified
23 in subsection (c), the Secretary shall publish in the
24 Federal Register the amount of the fees under para-
25 graph (1) for such fiscal year.

1 “(b) FEE REVENUE AMOUNTS.—

2 “(1) FISCAL YEAR 2019.—For fiscal year 2019,
3 fees under subsection (a)(1) shall be established to
4 generate a total facility fee revenue amount equal to
5 the sum of—

6 “(A) the annual base revenue for fiscal
7 year 2019 (as determined under paragraph
8 (3));

9 “(B) the dollar amount equal to the oper-
10 ating reserve adjustment for the fiscal year, if
11 applicable (as determined under subsection
12 (c)(2)); and

13 “(C) additional direct cost adjustments (as
14 determined under subsection (c)(3)).

15 “(2) SUBSEQUENT FISCAL YEARS.—For each of
16 the fiscal years 2020 through 2023, fees under sub-
17 section (a)(1) shall be established to generate a total
18 facility fee revenue amount equal to the sum of—

19 “(A) the annual base revenue for the fiscal
20 year (as determined under paragraph (3));

21 “(B) the dollar amount equal to the infla-
22 tion adjustment for the fiscal year (as deter-
23 mined under subsection (c)(1));

24 “(C) the dollar amount equal to the oper-
25 ating reserve adjustment for the fiscal year, if

1 applicable (as determined under subsection
2 (c)(2));

3 “(D) additional direct cost adjustments (as
4 determined under subsection (c)(3)); and

5 “(E) additional dollar amounts for each
6 fiscal year as follows:

7 “(i) \$7,000,000 for fiscal year 2020.

8 “(ii) \$6,000,000 for fiscal year 2021.

9 “(iii) \$7,000,000 for fiscal year 2022.

10 “(iv) \$3,000,000 for fiscal year 2023.

11 “(3) ANNUAL BASE REVENUE.—For purposes
12 of paragraphs (1)(A) and (2)(A), the dollar amount
13 of the annual base revenue for a fiscal year shall
14 be—

15 “(A) for fiscal year 2019, \$8,000,000; and

16 “(B) for fiscal years 2020 through 2023,
17 the dollar amount of the total revenue amount
18 established under this subsection for the pre-
19 vious fiscal year, not including any adjustments
20 made under subsection (c)(2) or (c)(3).

21 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

22 “(1) INFLATION ADJUSTMENT.—

23 “(A) IN GENERAL.—For purposes of sub-
24 section (b)(2)(B), the dollar amount of the in-
25 flation adjustment to the annual base revenue

1 for fiscal year 2020 and each subsequent fiscal
2 year shall be equal to the product of—

3 “(i) such annual base revenue for the
4 fiscal year under subsection (b)(2); and

5 “(ii) the inflation adjustment percent-
6 age under subparagraph (C).

7 “(B) OTC MONOGRAPH ORDER REQUEST
8 FEES.—For purposes of subsection (a)(2), the
9 dollar amount of the inflation adjustment to the
10 fee for OTC monograph order requests for fis-
11 cal year 2020 and each subsequent fiscal year
12 shall be equal to the product of—

13 “(i) the applicable fee under sub-
14 section (a)(2) for the preceding fiscal year;
15 and

16 “(ii) the inflation adjustment percent-
17 age under subparagraph (C).

18 “(C) INFLATION ADJUSTMENT PERCENT-
19 AGE.—The inflation adjustment percentage
20 under this subparagraph for a fiscal year is
21 equal to—

22 “(i) for each of fiscal years 2020 and
23 2021, the average annual percent change
24 that occurred in the Consumer Price Index
25 for urban consumers (Washington-Balti-

1 more, DC–MD–VA–WV; Not Seasonally
2 Adjusted; All items; Annual Index) for the
3 first 3 years of the preceding 4 years of
4 available data; and

5 “(ii) for each of fiscal years 2022 and
6 2023, the sum of—

7 “(I) the average annual percent
8 change in the cost, per full-time equiv-
9 alent position of the Food and Drug
10 Administration, of all personnel com-
11 pensation and benefits paid with re-
12 spect to such positions for the first 3
13 years of the preceding 4 fiscal years,
14 multiplied by the proportion of per-
15 sonnel compensation and benefits
16 costs to total costs of OTC mono-
17 graph drug activities for the first 3
18 years of the preceding 4 fiscal years;
19 and

20 “(II) the average annual percent
21 change that occurred in the Consumer
22 Price Index for urban consumers
23 (Washington-Baltimore, DC–MD–VA–
24 WV; Not Seasonally Adjusted; All
25 items; Annual Index) for the first 3

1 years of the preceding 4 years of
2 available data multiplied by the pro-
3 portion of all costs other than per-
4 sonnel compensation and benefits
5 costs to total costs of OTC mono-
6 graph drug activities for the first 3
7 years of the preceding 4 fiscal years.

8 “(2) OPERATING RESERVE ADJUSTMENT.—

9 “(A) IN GENERAL.—For fiscal year 2019
10 and subsequent fiscal years, for purposes of
11 subsections (b)(1)(B) and (b)(2)(C), the Sec-
12 retary may, in addition to adjustments under
13 paragraph (1), further increase the fee revenue
14 and fees if such an adjustment is necessary to
15 provide operating reserves of carryover user
16 fees for OTC monograph drug activities for not
17 more than the number of weeks specified in
18 subparagraph (B).

19 “(B) NUMBER OF WEEKS.—The number of
20 weeks specified in this subparagraph is—

21 “(i) 3 weeks for fiscal year 2019;

22 “(ii) 7 weeks for fiscal year 2020;

23 “(iii) 10 weeks for fiscal year 2021;

24 “(iv) 10 weeks for fiscal year 2022;

25 and

1 “(v) 10 weeks for fiscal year 2023.

2 “(C) DECREASE.—If the Secretary has
3 carryover balances for such process in excess of
4 10 weeks of the operating reserves referred to
5 in subparagraph (A), the Secretary shall de-
6 crease the fee revenue and fees referred to in
7 such subparagraph to provide for not more than
8 10 weeks of such operating reserves.

9 “(D) RATIONALE FOR ADJUSTMENT.—If
10 an adjustment under this paragraph is made,
11 the rationale for the amount of the increase or
12 decrease (as applicable) in fee revenue and fees
13 shall be contained in the annual Federal Reg-
14 ister notice under paragraph (4) establishing
15 fee revenue and fees for the fiscal year involved.

16 “(3) ADDITIONAL DIRECT COST ADJUST-
17 MENT.—The Secretary shall, in addition to adjust-
18 ments under paragraphs (1) and (2), further in-
19 crease the fee revenue and fees for purposes of sub-
20 section (b)(2)(D) by an amount equal to—

21 “(A) \$14,000,000 for fiscal year 2019;

22 “(B) \$7,000,000 for fiscal year 2020;

23 “(C) \$4,000,000 for fiscal year 2021;

24 “(D) \$3,000,000 for fiscal year 2022; and

25 “(E) \$3,000,000 for fiscal year 2023.

1 “(4) ANNUAL FEE SETTING.—

2 “(A) FISCAL YEAR 2019.—The Secretary
3 shall, not later than the second Monday in
4 March of 2019—

5 “(i) establish OTC monograph drug
6 facility fees for fiscal year 2019 under sub-
7 section (a), based on the revenue amount
8 for such year under subsection (b) and the
9 adjustments provided under this sub-
10 section; and

11 “(ii) publish fee revenue, facility fees,
12 and OTC monograph order requests in the
13 Federal Register.

14 “(B) SUBSEQUENT FISCAL YEARS.—The
15 Secretary shall, not later than the second Mon-
16 day in March of each fiscal year that begins
17 after September 30, 2019—

18 “(i) establish for each such fiscal
19 year, based on the revenue amounts under
20 subsection (b) and the adjustments pro-
21 vided under this subsection—

22 “(I) OTC monograph drug facil-
23 ity fees under subsection (a)(1); and

1 “(II) OTC monograph order re-
2 quest fees under subsection (a)(2);
3 and

4 “(ii) publish such fee revenue
5 amounts, facility fees, and OTC mono-
6 graph order request fees in the Federal
7 Register.

8 “(d) IDENTIFICATION OF FACILITIES.—Each person
9 that owns an OTC monograph drug facility shall submit
10 to the Secretary the information required under this sub-
11 section each year. Such information shall, for each fiscal
12 year—

13 “(1) be submitted as part of the requirements
14 for drug establishment registration set forth in sec-
15 tion 510; and

16 “(2) include for each such facility, at a min-
17 imum, identification of the facility’s business oper-
18 ation as that of an OTC monograph drug facility.

19 “(e) EFFECT OF FAILURE TO PAY FEES.—

20 “(1) OTC MONOGRAPH DRUG FACILITY FEE.—

21 “(A) IN GENERAL.—Failure to pay the fee
22 under subsection (a)(1) within 20 calendar days
23 of the due date as specified in subparagraph
24 (D) of such subsection shall result in the fol-
25 lowing:

1 “(i) The Secretary shall place the fa-
2 cility on a publicly available arrears list.

3 “(ii) All OTC monograph drugs man-
4 ufactured in such a facility or containing
5 an ingredient manufactured in such a facil-
6 ity shall be deemed misbranded under sec-
7 tion 502(ff).

8 “(B) APPLICATION OF PENALTIES.—The
9 penalties under this paragraph shall apply until
10 the fee established by subsection (a)(1) is paid.

11 “(2) ORDER REQUESTS.—An OTC monograph
12 order request submitted by a person subject to fees
13 under subsection (a) shall be considered incomplete
14 and shall not be accepted for filing by the Secretary
15 until all fees owed by such person under this section
16 have been paid.

17 “(3) MEETINGS.—A person subject to fees
18 under this section shall be considered ineligible for
19 OTC monograph drug meetings until all such fees
20 owed by such person have been paid.

21 “(f) CREDITING AND AVAILABILITY OF FEES.—

22 “(1) IN GENERAL.—Fees authorized under sub-
23 section (a) shall be collected and available for obliga-
24 tion only to the extent and in the amount provided
25 in advance in appropriations Acts. Such fees are au-

1 thorized to remain available until expended. Such
2 sums as may be necessary may be transferred from
3 the Food and Drug Administration salaries and ex-
4 penses appropriation account without fiscal year lim-
5 itation to such appropriation account for salaries
6 and expenses with such fiscal year limitation. The
7 sums transferred shall be available solely for OTC
8 monograph drug activities.

9 “(2) COLLECTIONS AND APPROPRIATION
10 ACTS.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (C), the fees authorized by this section
13 shall be collected and available in each fiscal
14 year in an amount not to exceed the amount
15 specified in appropriation Acts, or otherwise
16 made available for obligation, for such fiscal
17 year.

18 “(B) USE OF FEES AND LIMITATION.—
19 The fees authorized by this section shall be
20 available to defray increases in the costs of the
21 resources allocated for OTC monograph drug
22 activities (including increases in such costs for
23 an additional number of full-time equivalent po-
24 sitions in the Department of Health and
25 Human Services to be engaged in such activi-

1 ties), only if the Secretary allocates for such
2 purpose an amount for such fiscal year (exclud-
3 ing amounts from fees collected under this sec-
4 tion) no less than \$12,000,000, multiplied by
5 the adjustment factor applicable to the fiscal
6 year involved under subsection (c)(1).

7 “(C) COMPLIANCE.—The Secretary shall
8 be considered to have met the requirements of
9 subparagraph (B) in any fiscal year if the costs
10 funded by appropriations and allocated for OTC
11 monograph drug activities are not more than 15
12 percent below the level specified in such sub-
13 paragraph.

14 “(D) PROVISION FOR EARLY PAYMENTS IN
15 SUBSEQUENT YEARS.—Payment of fees author-
16 ized under this section for a fiscal year (after
17 fiscal year 2019), prior to the due date for such
18 fees, may be accepted by the Secretary in ac-
19 cordance with authority provided in advance in
20 a prior year appropriations Act.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—
22 For each of the fiscal years 2019 through 2023,
23 there is authorized to be appropriated for fees under
24 this section an amount equal to the total amount of
25 fees assessed for such fiscal year under this section.

1 “(g) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 calendar days after
4 it is due, such fee shall be treated as a claim of the United
5 States Government subject to subchapter II of chapter 37
6 of title 31, United States Code.

7 “(h) CONSTRUCTION.—This section may not be con-
8 strued to require that the number of full-time equivalent
9 positions in the Department of Health and Human Serv-
10 ices, for officers, employers, and advisory committees not
11 engaged in OTC monograph drug activities, be reduced
12 to offset the number of officers, employees, and advisory
13 committees so engaged.

14 **“SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-**
15 **MENTS.**

16 “(a) PERFORMANCE REPORT.—Beginning with fiscal
17 year 2019, and not later than 120 calendar days after the
18 end of each fiscal year thereafter for which fees are col-
19 lected under this part, the Secretary shall prepare and
20 submit to the Committee on Energy and Commerce of the
21 House of Representatives and the Committee on Health,
22 Education, Labor, and Pensions of the Senate a report
23 concerning the progress of the Food and Drug Adminis-
24 tration in achieving the goals identified in the letters de-
25 scribed in section 2001(b) of the Over-the-Counter Mono-

1 graph Safety, Innovation, and Reform Act of 2018 during
2 such fiscal year and the future plans of the Food and
3 Drug Administration for meeting such goals.

4 “(b) FISCAL REPORT.—Not later than 120 calendar
5 days after the end of fiscal year 2019 and each subsequent
6 fiscal year for which fees are collected under this part,
7 the Secretary shall prepare and submit to the Committee
8 on Energy and Commerce of the House of Representatives
9 and the Committee on Health, Education, Labor, and
10 Pensions of the Senate a report on the implementation
11 of the authority for such fees during such fiscal year and
12 the use, by the Food and Drug Administration, of the fees
13 collected for such fiscal year.

14 “(c) PUBLIC AVAILABILITY.—The Secretary shall
15 make the reports required under subsections (a) and (b)
16 available to the public on the internet website of the Food
17 and Drug Administration.

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-
20 ommendations to present to the Congress with re-
21 spect to the goals described in subsection (a), and
22 plans for meeting the goals, for OTC monograph
23 drug activities for the first 5 fiscal years after fiscal
24 year 2023, and for the reauthorization of this part

1 for such fiscal years, the Secretary shall consult
2 with—

3 “(A) the Committee on Energy and Com-
4 merce of the House of Representatives;

5 “(B) the Committee on Health, Education,
6 Labor, and Pensions of the Senate;

7 “(C) scientific and academic experts;

8 “(D) health care professionals;

9 “(E) representatives of patient and con-
10 sumer advocacy groups; and

11 “(F) the regulated industry.

12 “(2) PUBLIC REVIEW OF RECOMMENDA-
13 TIONS.—After negotiations with the regulated indus-
14 try, the Secretary shall—

15 “(A) present the recommendations devel-
16 oped under paragraph (1) to the congressional
17 committees specified in such paragraph;

18 “(B) publish such recommendations in the
19 Federal Register;

20 “(C) provide for a period of 30 calendar
21 days for the public to provide written comments
22 on such recommendations;

23 “(D) hold a meeting at which the public
24 may present its views on such recommenda-
25 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2023, the Secretary
6 shall transmit to the Congress the revised rec-
7 ommendations under paragraph (2), a summary of
8 the views and comments received under such para-
9 graph, and any changes made to the recommenda-
10 tions in response to such views and comments.”.

Passed the House of Representatives December 20,
2018.

Attest:

Clerk.

115TH CONGRESS
2^D 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.