

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

# H. R. 7328

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## 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 serting “for either of the 2 imme-  
14 diately preceding fiscal years”; and

15 (II) by striking “2008” and in-  
16 serting “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’ means an injury that is greater than or equal  
4 to 15 on the injury severity score.  
5

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 igned by subsection (a)(6), is amended by striking  
6 “\$138,300,000 for each of fiscal years 2014 through  
7 2018” and inserting “\$161,800,000 for each of fiscal  
8 years 2019 through 2023”.

9 (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 capac-  
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;”;

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                   **PRIATE 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.*

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

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# 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.