

118TH CONGRESS
1ST SESSION

H. R. 4697

To amend the Public Health Service Act to reauthorize certain programs with respect to public health security and all-hazards preparedness and response related to the Administration for Strategic Preparedness and Response and certain programs with respect to public health security and all-hazards preparedness and response related to the Centers for Disease Control and Prevention, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2023

Ms. SCHRIER (for herself, Ms. ESHOO, Mr. PALLONE, Ms. DEGETTE, Ms. SCHAKOWSKY, Ms. MATSUI, Ms. CASTOR of Florida, Mr. SARBANES, Mr. TONKO, Ms. CLARKE of New York, Mr. CÁRDENAS, Mr. RUIZ, Mr. PETERS, Mrs. DINGELL, Mr. VEASEY, Ms. KUSTER, Ms. KELLY of Illinois, Ms. BARRAGÁN, Ms. BLUNT ROCHESTER, Mr. SOTO, Ms. CRAIG, Mrs. TRAHAN, and Mrs. FLETCHER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to reauthorize certain programs with respect to public health security and all-hazards preparedness and response related to the Administration for Strategic Preparedness and Response and certain programs with respect to public health security and all-hazards preparedness and response related to the Centers for Disease Control and Prevention, 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 “Protecting Pandemic and All-Hazards Preparedness Act
 6 of 2023” or the “Protecting PAHPA Act of 2023”.

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

Sec. 1. Short title; table of contents.

TITLE I—PREPARING FOR AND RESPONDING TO PUBLIC
 HEALTH SECURITY THREATS

- Sec. 101. National health security strategy.
- Sec. 102. Protection of national security from threats.
- Sec. 103. Partnerships for State and regional hospital preparedness to improve surge capacity.
- Sec. 104. Guidelines for regional health care emergency preparedness and response systems.
- Sec. 105. Strategic National Stockpile.
- Sec. 106. Diagnostic testing preparedness plan.
- Sec. 107. Biomedical Advanced Research and Development Authority.
- Sec. 108. Ensuring collaboration and coordination in medical countermeasure development.
- Sec. 109. Review of ASPR efforts to ensure supply chain resiliency and accountability.
- Sec. 110. Review of HHS efforts To ensure rapid production and domestic manufacturing capacity of medical countermeasures.
- Sec. 111. Crisis standards of care.

TITLE II—ENSURING WORKFORCE TO PREPARE FOR AND
 RESPOND TO PUBLIC HEALTH SECURITY THREATS

- Sec. 201. Emergency system for advance registration of volunteer health professional.
- Sec. 202. Military and civilian partnership for trauma readiness.
- Sec. 203. National advisory committees on disasters.
- Sec. 204. National Disaster Medical System.
- Sec. 205. Volunteer Medical Reserve Corps.

TITLE III—PREPARING FOR AND RESPONDING TO PUBLIC
 HEALTH SECURITY THREATS

- Sec. 301. Improving State and local public health security.
- Sec. 302. Facilities and capacities of the Centers for Disease Control and Prevention to combat public health security threats.
- Sec. 303. Monitoring and distribution of certain medical countermeasures.

- Sec. 304. Enhanced control of dangerous biological agents and toxins.
 Sec. 305. Mosquito-borne diseases.
 Sec. 306. Epidemiology-laboratory capacity.
 Sec. 307. Supporting public health data availability and access.

TITLE IV—ENSURING WORKFORCE TO PREPARE FOR AND
 RESPOND TO PUBLIC HEALTH SECURITY THREATS

- Sec. 401. Temporary reassignment of State and local personnel during a public health emergency.
 Sec. 402. Epidemic Intelligence Service.

TITLE V—ADDRESSING DRUG AND SUPPLY CHAIN SHORTAGES

Subtitle A—Ensuring Access to Lifesaving Drugs

- Sec. 501. Extended expiration dates for life-saving drugs.

Subtitle B—Drug Origin Transparency

- Sec. 511. Enhanced drug manufacturing amount information reporting.
 Sec. 512. Require drug labeling to include original manufacturer and supply chain information.

Subtitle C—Medical Device Shortage Reduction

- Sec. 521. Clarifying device shortage notifications.
 Sec. 522. Supply chain risk management.
 Sec. 523. Clarifying voluntary notifications.

Subtitle D—Drug Shortage Prevention

- Sec. 531. Improving notification procedures in case of increased demand for critical essential medicines.

Subtitle E—Protecting Americans From Unsafe Drugs

- Sec. 541. Notification, nondistribution, and recall of drugs.

1 **TITLE I—PREPARING FOR AND**
 2 **RESPONDING TO PUBLIC**
 3 **HEALTH SECURITY THREATS**

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

- 5 (a) PUBLIC HEALTH WORKFORCE.—Section
 6 2802(a)(3) of the Public Health Service Act (42 U.S.C.
 7 300hh–1(a)(3)) is amended by striking “In 2022, the”
 8 and inserting “The”.

1 (b) MEDICAL AND PUBLIC HEALTH COMMUNITY
2 PREPAREDNESS GOAL.—Section 2802(b)(8)(A) of the
3 Public Health Service Act (42 U.S.C. 300hh–1(b)(8)(A))
4 is amended by inserting before the semicolon the following:
5 “, including by protecting against cybersecurity threats”.

6 (c) CYBERSECURITY RESILIENCY OF HEALTH CARE
7 DELIVERY SYSTEMS.—Section 2802(b) of the Public
8 Health Service Act (42 U.S.C. 300hh–1(b)) is amended
9 by adding at the end the following:

10 “(11) CYBERSECURITY RESILIENCY OF HEALTH
11 CARE DELIVERY SYSTEMS.—Strengthening the abil-
12 ity of States, local communities, Tribal communities,
13 and territorial entities to protect against, mitigate,
14 or otherwise address the impact of cybersecurity
15 risks or cybersecurity attacks that affect public
16 health through mechanisms (including awards of
17 grants or cooperative agreements under section
18 319C–2) that encourage hospitals and other facili-
19 ties involved in the delivery of health care items and
20 services to use recognized security practices meeting
21 or exceeding the approaches promulgated under sec-
22 tion 405(d) of the Cybersecurity Act of 2015.”.

1 **SEC. 102. PROTECTION OF NATIONAL SECURITY FROM**
2 **THREATS.**

3 Section 2811(f)(2)(A) of the Public Health Service
4 Act (42 U.S.C. 300hh–10(f)(2)(A)) is amended by strik-
5 ing “\$250,000,000 for each of fiscal years 2019 through
6 2023” and inserting “\$327,991,000 for each of fiscal
7 years 2024 through 2028”.

8 **SEC. 103. PARTNERSHIPS FOR STATE AND REGIONAL HOS-**
9 **PITAL PREPAREDNESS TO IMPROVE SURGE**
10 **CAPACITY.**

11 (a) **AUTHORIZATION OF APPROPRIATIONS.**—Section
12 319C–2(j)(1)(A) of the Public Health Service Act (42
13 U.S.C. 247d–3b(j)(1)(A)) is amended—

14 (1) by striking “is authorized to be appro-
15 priated” and inserting “are authorized to be appro-
16 priated”; and

17 (2) by inserting “ and \$500,000,000 for each of
18 fiscal years 2024 through 2028” before the period at
19 the end.

20 (b) **SUNSET.**—Section 319C–2(j)(1)(B)(iii) of the
21 Public Health Service Act (42 U.S.C. 247d–
22 3b(j)(1)(B)(iii)) is amended by striking “2023” and in-
23 serting “2028”.

1 **SEC. 104. GUIDELINES FOR REGIONAL HEALTH CARE**
2 **EMERGENCY PREPAREDNESS AND RESPONSE**
3 **SYSTEMS.**

4 (a) **GUIDELINES.**—Section 319C–3(b)(3) of the Pub-
5 lic Health Service Act (42 U.S.C. 247d–3c(b)(3)) is
6 amended by striking “the Pandemic and All-Hazards Pre-
7 paredness and Advancing Innovation Act of 2019 (includ-
8 ing any amendments made by such Act)” and inserting
9 “the Pandemic and All-Hazards Preparedness and Ad-
10 vancing Innovation Act of 2019, the PREVENT
11 Pandemics Act (title II of division FF of Public Law 117–
12 328), and the Protecting Pandemic and All-Hazards Pre-
13 paredness Act of 2023”.

14 (b) **DEMONSTRATION PROJECT FOR REGIONAL**
15 **HEALTH CARE PREPAREDNESS AND RESPONSE SYS-**
16 **TEMS.**—Section 319C–3(e)(2) of the Public Health Serv-
17 ice Act (42 U.S.C. 247d–3c(e)(2)) is amended by striking
18 “2023” and inserting “2028”.

19 **SEC. 105. STRATEGIC NATIONAL STOCKPILE.**

20 (a) **VENDOR-MANAGED INVENTORY AND WARM-**
21 **BASED SURGE CAPACITY CONTRACTS AND COOPERATIVE**
22 **AGREEMENTS WITH CLINICAL LABORATORIES.**—Section
23 319F–2(a)(5)(A) of the Public Health Service Act (42
24 U.S.C. 247d–6b(a)(5)(A)) is amended—

25 (1) by inserting after “contracts or cooperative
26 agreements with vendors, which may include manu-

1 facturers or distributors of medical products,” the
2 following: “as well as clinical laboratories,”; and

3 (2) in clause (ii), by striking “domestic manu-
4 facturing capacity” and inserting “domestic manu-
5 facturing and laboratory capacity”.

6 (b) AUTHORIZATION OF APPROPRIATIONS.—

7 (1) IN GENERAL.—Section 319F–2(f) of the
8 Public Health Service Act (42 U.S.C. 247d–6b(f)) is
9 amended—

10 (A) in paragraph (1), by striking
11 “\$610,000,000 for each of fiscal years 2019
12 through 2021, and \$750,000,000 for each of
13 fiscal years 2022 and 2023” and inserting
14 “\$1,963,000,000 for each of fiscal years 2024
15 through 2028”;

16 (B) by striking paragraph (2); and

17 (C) by striking “AUTHORIZATION OF AP-
18 PROPRIATIONS” and all that follows through
19 “For the purpose of carrying out subsection
20 (a), there are authorized to be appropriated”
21 and inserting “AUTHORIZATION OF APPROPRIA-
22 TIONS.—For the purpose of carrying out sub-
23 section (a), there is authorized to be appro-
24 priated”.

1 (2) PILOT PROGRAM TO SUPPORT STATE MED-
2 ICAL STOCKPILES.—Section 319F–2(i)(9) of the
3 Public Health Service Act (42 U.S.C. 247d–6b(i)(9))
4 is amended by striking “2024” and inserting
5 “2028”.

6 **SEC. 106. DIAGNOSTIC TESTING PREPAREDNESS PLAN.**

7 The Public Health Service Act (42 U.S.C. 201 et
8 seq.) is amended by inserting after section 319F–5 of such
9 Act (42 U.S.C. 247d–6f) the following:

10 **“SEC. 319F–6. DIAGNOSTIC TESTING PREPAREDNESS PLAN.**

11 “(a) IN GENERAL.—The Secretary, acting through
12 the Assistant Secretary for Preparedness and Response,
13 and in consultation with the heads of relevant Federal
14 agencies, shall develop not later than 1 year after the date
15 of enactment of this section and update not less than every
16 3 years thereafter a plan for rapid development, authoriza-
17 tion, scaling, procurement, and distribution of diagnostics
18 and clinical and diagnostic laboratory testing capacity dur-
19 ing a public health emergency declared under section 319.

20 “(b) PURPOSES.—The purposes of the plan under
21 subsection (a) shall be—

22 “(1) to facilitate the development and utiliza-
23 tion of diagnostics for use with respect to a novel
24 chemical, biological, radiological, or nuclear threat or
25 an emerging infectious disease, including any such

1 high-throughput laboratory diagnostic, point-of-care
2 diagnostic, or rapid at-home or point-of-use diag-
3 nostic; and

4 “(2) to describe the processes for rapid develop-
5 ment, authorization, scaling, procurement, and dis-
6 tribution of diagnostics and clinical and diagnostic
7 laboratory testing capacity.

8 “(c) PUBLIC-PRIVATE COORDINATION.—

9 “(1) IN GENERAL.—The Secretary, acting
10 through the Assistant Secretary for Preparedness
11 and Response, shall include within the plan under
12 subsection (a) a plan for public-private coordination
13 on national diagnostic testing during a public health
14 emergency.

15 “(2) CONTENTS.—The plan under paragraph
16 (1) shall be designed to facilitate coordination and
17 collaboration among—

18 “(A) government agencies; and

19 “(B) critical private-sector diagnostic test-
20 ing stakeholders, including private-sector clin-
21 ical and diagnostic laboratories, diagnostic man-
22 ufacturers, health care product distributors,
23 and research laboratories.

24 “(d) PUBLIC AVAILABILITY.—The Secretary, acting
25 through the Assistant Secretary for Preparedness and Re-

1 sponse, shall make the plan under subsection (a) publicly
2 available.

3 “(e) **REPORTS TO CONGRESS.**—Not later than 1 year
4 after commencing implementation of the plan under sub-
5 section (a) for a public health emergency, the Secretary,
6 acting through the Assistant Secretary for Preparedness
7 and Response, shall submit to the Congress a report evalu-
8 ating the effectiveness of activities implemented under the
9 plan.”.

10 **SEC. 107. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
11 **OPMENT AUTHORITY.**

12 (a) **MEDICAL COUNTERMEASURES FOR VIRAL**
13 **THREATS WITH PANDEMIC POTENTIAL.**—Section
14 319L(c)(4) of the Public Health Service Act (42 U.S.C.
15 247d–7e(c)(4)) is amended—

16 (1) in subparagraph (D)—

17 (A) in clause (ii), by striking “; and” and
18 inserting a semicolon;

19 (B) by redesignating clause (iii) as clause
20 (v); and

21 (C) by inserting after clause (ii) the fol-
22 lowing:

23 “(iii) the identification and develop-
24 ment of platform manufacturing tech-
25 nologies needed for advanced development

1 and manufacturing of medical counter-
2 measures for viral families which have sig-
3 nificant potential to cause a pandemic;

4 “(iv) advanced research and develop-
5 ment of flexible medical countermeasures
6 against priority respiratory virus families
7 and other respiratory viral pathogens with
8 a significant potential to cause a pandemic,
9 with both pathogen-specific and pathogen-
10 agnostic approaches; and”; and

11 (2) in subparagraph (F)—

12 (A) in clause (ii), by striking “; and” at
13 the end and inserting a semicolon;

14 (B) in clause (iii), by striking the period
15 and inserting “; and”; and

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

17 “(iv) priority virus families and other
18 viral pathogens with a significant potential
19 to cause a pandemic.”.

20 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
21 319L(d)(2) of the Public Health Service Act (42 U.S.C.
22 247d–7e(d)(2)) is amended by striking “\$611,700,000 for
23 each of fiscal years 2019 through 2023” and inserting
24 “\$950,000,000 for each of fiscal years 2024 through
25 2028”.

1 (c) INAPPLICABILITY OF CERTAIN PROVISIONS SUN-
2 SET.—Section 319L(e)(1)(D) of the Public Health Service
3 Act (42 U.S.C. 247d–7e(e)(1)(D)) is amended by striking
4 “on the date that is 17 years after the date of enactment
5 of the Pandemic and All-Hazards Preparedness Act” and
6 inserting “on October 1, 2028”.

7 **SEC. 108. ENSURING COLLABORATION AND COORDINATION**
8 **IN MEDICAL COUNTERMEASURE DEVELOP-**
9 **MENT.**

10 Section 319L–1(b) of the Public Health Service Act
11 (42 U.S.C. 274d–7f(b)) is amended by striking “at the
12 end of the 17-year period that begins on the date of enact-
13 ment of this Act” and inserting “on October 1, 2028”.

14 **SEC. 109. REVIEW OF ASPR EFFORTS TO ENSURE SUPPLY**
15 **CHAIN RESILIENCY AND ACCOUNTABILITY.**

16 (a) IN GENERAL.—Not later than 18 months after
17 the date of enactment of this Act, the Comptroller General
18 of the United States shall complete a review of—

19 (1) the Supply Chain Control Tower Program
20 (in this section referred to as the “SCCT Program”)
21 under the Administration for Strategic Preparedness
22 and Response of the Department of Health and
23 Human Services; and

24 (2) any related efforts of the Administration for
25 Strategic Preparedness and Response—

1 (A) to create supply chain visibility into in-
2 ventory, capacity, and distribution flow of cer-
3 tain products critical to preparedness and re-
4 sponse efforts;

5 (B) to provide insights into demand fore-
6 casting and modeling of certain products crit-
7 ical to preparedness and response efforts; or

8 (C) to inform preparedness and response
9 efforts by targeting distribution and coordi-
10 nating supply with demand for certain products
11 critical to preparedness and response efforts.

12 (b) ISSUES.—The review under this section shall in-
13 clude examination of—

14 (1) the data being collected and maintained
15 pursuant to the SCCT Program;

16 (2) how the Department of Health and Human
17 Services, acting through the Administration for
18 Strategic Preparedness and Response, uses such
19 data to provide supply chain visibility and address
20 actual or potential supply gaps;

21 (3) the extent to which such data is provided
22 and shared with end users, including States, local-
23 ities, Territories, Tribes, and industry partners;

1 (4) the frequency and cadence of data reporting
2 and sharing by and among States, localities, Terri-
3 tories, Tribes, and industry partners;

4 (5) information related to the type and number
5 of States, localities, Territories, Tribes, and industry
6 partners participating in the SCCT Program;

7 (6) the process by which States, localities, Ter-
8 ritories, Tribes, and industry partners voluntarily
9 choose to participate in the SCCT Program; and

10 (7) any inefficiencies, deficiencies, or challenges
11 related to the application or operation of the SCCT
12 Program.

13 (c) REPORT TO CONGRESS.—Not later than the dead-
14 line described in subsection (a) for the completion of the
15 review under this section, the Comptroller General shall
16 submit to the Committee on Energy and Commerce of the
17 House of Representatives and the Committee on Health,
18 Education, Labor, and Pensions of the Senate a report
19 on the results of such review.

20 **SEC. 110. REVIEW OF HHS EFFORTS TO ENSURE RAPID**
21 **PRODUCTION AND DOMESTIC MANUFAC-**
22 **TURING CAPACITY OF MEDICAL COUNTER-**
23 **MEASURES.**

24 (a) IN GENERAL.—Not later than 1 year after the
25 date of the enactment of this Act, the Comptroller General

1 of the United States shall conduct and complete a review
2 examining the efforts of the Secretary of Health and
3 Human Services to ensure that the United States is pre-
4 pared to rapidly produce qualified countermeasures (as de-
5 fined in section 319F–1 of the Public Health Service Act
6 (42 U.S.C. 247d–6a)) in the event of a public health emer-
7 gency declared under section 319 of the Public Health
8 Service Act (42 U.S.C. 274d).

9 (b) CONTENTS.—The review conducted under sub-
10 section (a) shall include a review of—

11 (1) the efforts described in such subsection, in-
12 cluding the Secretary’s efforts to transition from the
13 Centers for Innovation and Advanced Drug Manu-
14 facturing program to any new efforts, including the
15 National Biopharmaceutical Manufacturing Partner-
16 ship and Industrial Base Expansion Connect;

17 (2) the progress made toward the implementa-
18 tion of such efforts; and

19 (3) the planning within the Department of
20 Health and Human Services to assess risks and
21 challenges associated with advanced development
22 and manufacturing of qualified countermeasures.

23 (c) REPORT TO CONGRESS.—Not later than 1 year
24 after completing the review under subsection (a), the

1 Comptroller General of the United States shall submit to
2 the Congress a report containing—

3 (1) the results of the review; and

4 (2) the Comptroller General’s recommendations
5 for ensuring that the United States is prepared to
6 rapidly produce qualified countermeasures in the
7 event of a public health emergency.

8 **SEC. 111. CRISIS STANDARDS OF CARE.**

9 Not later than 2 years after the date of enactment
10 of this Act, the Secretary of Health and Human Services,
11 acting through the Director of the Office for Civil Rights
12 of the Department of Health and Human Services, shall
13 issue guidance on how to develop or modify State and local
14 crisis standards of care for use during an emergency pe-
15 riod (as defined in section 1135(g)(1) of the Social Secu-
16 rity Act (42 U.S.C. 1320b–5(g)(1)) so as to bring such
17 standards of care into compliance with the nondiscrimina-
18 tion requirements of section 504 of the Rehabilitation Act
19 of 1973 (29 U.S.C. 794).

1 **TITLE II—ENSURING WORK-**
2 **FORCE TO PREPARE FOR AND**
3 **RESPOND TO PUBLIC HEALTH**
4 **SECURITY THREATS**

5 **SEC. 201. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
6 **TION OF VOLUNTEER HEALTH PROFES-**
7 **SIONAL.**

8 (a) IN GENERAL.—Section 319I(a) of the Public
9 Health Service Act (42 U.S.C. 247d–7b) is amended by
10 striking “Not later than 12 months after the date of en-
11 actment of the Pandemic and All-Hazards Preparedness
12 Act, the Secretary shall link existing State verification sys-
13 tems to maintain” and inserting “The Secretary shall con-
14 tinue to maintain”.

15 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
16 319I(k) of the Public Health Service Act (42 U.S.C.
17 247d–7b(k)) is amended by striking “2019 through 2023”
18 and inserting “2024 through 2028”.

19 **SEC. 202. MILITARY AND CIVILIAN PARTNERSHIP FOR**
20 **TRAUMA READINESS.**

21 Section 1291(g) of the Public Health Service Act (42
22 U.S.C. 300d–91(g)) is amended by striking “2019
23 through 2023” and inserting “2024 through 2028”.

1 **SEC. 203. NATIONAL ADVISORY COMMITTEES ON DISAS-**
2 **TERS.**

3 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN
4 AND DISASTERS.—Subsection (g) of section 2811A of the
5 Public Health Service Act (42 U.S.C. 300hh–10b) is
6 amended to read as follows:

7 “(g) SUNSET.—

8 “(1) IN GENERAL.—The Advisory Committee
9 shall terminate on September 30, 2028.

10 “(2) EXTENSION OF COMMITTEE.—Not later
11 than October 1, 2027, the Secretary shall submit to
12 Congress a recommendation on whether the Advisory
13 Committee should be extended.”.

14 (b) NATIONAL ADVISORY COMMITTEE ON SENIORS
15 AND DISASTERS.—Section 2811B of the Public Health
16 Service Act (42 U.S.C. 300hh–10c) is amended—

17 (1) in subsection (d)—

18 (A) in paragraph (1), by striking “in con-
19 sultation with such other heads of agencies as
20 appropriate, shall appoint not more than 17
21 members” and inserting “in consultation with
22 such other Secretaries as may be appropriate,
23 shall appoint not more than 23 members”;

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

1 (C) by amending paragraph (3), as so re-
2 designated—

3 (i) in the paragraph heading, by strik-
4 ing “REQUIRED MEMBERS” and inserting
5 “REQUIRED FEDERAL MEMBERS”;

6 (ii) in the matter preceding subpara-
7 graph (A), by striking “and non-Federal
8 members,”;

9 (iii) by striking subparagraphs (J)
10 and (K); and

11 (iv) by redesignating subparagraph
12 (L) as subparagraph (J);

13 (D) by inserting after paragraph (1) the
14 following new paragraph:

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

20 “(A) at least 4 non-Federal health care
21 providers with expertise in geriatric medical dis-
22 aster planning, preparedness, response, or re-
23 covery;

24 “(B) at least 3 representatives of State,
25 local, Tribal, or territorial agencies with exper-

1 tise in geriatric disaster planning, preparedness,
2 response, or recovery; and

3 “(C) at least 4 non-Federal professionals
4 with training in gerontology, including social
5 workers, scientists, human services specialists,
6 or other non-medical professionals, with experi-
7 ence in disaster planning, preparedness, re-
8 sponse, or recovery among other adults.”; and

9 (E) by adding at the end the following new
10 paragraphs:

11 “(4) TERM OF APPOINTMENT.—Each member
12 of the Advisory Committee appointed under para-
13 graph (2) shall serve for a term of 3 years, except
14 that the Secretary may adjust the terms of the Advi-
15 sory Committee appointees serving on the date of
16 enactment of the Preparing for All Hazards and
17 Pathogens Reauthorization Act, or appointees who
18 are initially appointed after such date of enactment,
19 in order to provide for a staggered term of appoint-
20 ment for all members.

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

1 (2) in subsection (g)—

2 (A) in paragraph (1), by striking “2023”
3 and inserting “2028”; and

4 (B) in paragraph (2), by striking “2022”
5 and inserting “2027”.

6 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-
7 UALS WITH DISABILITIES.—Section 2811C of the Public
8 Health Service Act (42 U.S.C. 300hh–10d) is amended—

9 (1) by redesignating subsections (e) through (g)
10 as subsections (d) through (h), respectively;

11 (2) by inserting after subsection (b) the fol-
12 lowing new subsection:

13 “(c) ADDITIONAL DUTIES.—The Advisory Committee
14 may provide advice and recommendations to the Secretary
15 with respect to individuals with disabilities, and medical
16 and public health grants and cooperative agreements, as
17 applicable to preparedness and response activities under
18 this title and title III.”;

19 (3) in subsection (d), as so redesignated—

20 (A) in paragraph (1), by striking “in con-
21 sultation with such other heads of agencies and
22 departments as appropriate, shall appoint not
23 more than 17 members” and inserting “in con-
24 sultation with such other Secretaries as may be

1 appropriate, shall appoint not more than 23
2 members”;

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

5 (C) by amending paragraph (3), as reded-
6 igned—

7 (i) in the paragraph heading, by strik-
8 ing “REQUIRED MEMBERS” and inserting
9 “REQUIRED FEDERAL MEMBERS”;

10 (ii) in the matter preceding subpara-
11 graph (A), by striking “and non-Federal
12 members,”;

13 (iii) by striking subparagraph (K) and
14 inserting the following:

15 “(K) Representatives of such other Federal
16 agencies as the Secretary determines necessary
17 to fulfill the duties of the Advisory Com-
18 mittee.”; and

19 (iv) by striking subparagraphs (L)
20 and (M);

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

23 “(2) REQUIRED NON-FEDERAL MEMBERS.—The
24 Secretary, in consultation with such other heads of
25 Federal agencies as may be appropriate, shall ap-

1 point to the Advisory Committee under paragraph
2 (1) at least 13 individuals, including—

3 “(A) at least 4 non-Federal health care
4 professionals with expertise in disability accessi-
5 bility before, during, and after disasters, med-
6 ical and mass care disaster planning, prepared-
7 ness, response, or recovery;

8 “(B) at least 3 representatives from State,
9 local, Tribal, or territorial agencies with exper-
10 tise in disaster planning, preparedness, re-
11 sponse, or recovery for individuals with disabil-
12 ities; and

13 “(C) at least 4 individuals with a disability
14 with expertise in disaster planning, prepared-
15 ness, response, or recovery for individuals with
16 disabilities.”; and

17 (E) by adding at the end the following new
18 paragraphs:

19 “(4) TERM OF APPOINTMENT.—Each member
20 of the Advisory Committee appointed under para-
21 graph (2) shall serve for a term of 3 years, except
22 that the Secretary may adjust the terms of the Advi-
23 sory Committee appointees serving on the date of
24 enactment of the Preparing for All Hazards and
25 Pathogens Reauthorization Act, or appointees who

1 are initially appointed after such date of enactment,
2 in order to provide for a staggered term of appoint-
3 ment for all members.

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

9 (4) in subsection (g)—

10 (A) in paragraph (1), by striking “2023”
11 and inserting “2028”; and

12 (B) in paragraph (2), by striking “2022”
13 and inserting “2027”.

14 **SEC. 204. NATIONAL DISASTER MEDICAL SYSTEM.**

15 (a) ELIMINATION OF SUNSET OF AUTHORITY TO
16 MAKE CERTAIN APPOINTMENTS FOR NATIONAL DIS-
17 ASTER MEDICAL SYSTEM.—Section 2812(c)(4) of the
18 Public Health Service Act (42 U.S.C. 300hh–11(c)(4)) is
19 amended—

20 (1) by striking “(A) IN GENERAL.—If the Sec-
21 retary determines” and inserting “If the Secretary
22 determines”; and

23 (2) by striking subparagraph (B).

24 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
25 2812(g) of the Public Health Service Act (42 U.S.C.

1 300hh–11(g)) is amended by striking “\$57,400,000 for
2 each of fiscal years 2019 through 2023” and inserting
3 “\$96,904,000 for each of fiscal years 2024 through
4 2028”.

5 **SEC. 205. VOLUNTEER MEDICAL RESERVE CORPS.**

6 Section 2813(i) of the Public Health Service Act (42
7 U.S.C. 300hh–15(i)) is amended by striking “2019
8 through 2023” and inserting “2024 through 2028”.

9 **TITLE III—PREPARING FOR AND**
10 **RESPONDING TO PUBLIC**
11 **HEALTH SECURITY THREATS**

12 **SEC. 301. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
13 **SECURITY.**

14 (a) **AUTHORIZATION OF APPROPRIATIONS.**—Section
15 319C–1(h)(1)(A) of the Public Health Service Act (42
16 U.S.C. 247d–3a(h)(1)(A)) is amended by striking
17 “\$685,000,000 for each of fiscal years 2019 through
18 2023” and inserting “\$1,000,000,000 for each of fiscal
19 years 2024 through 2028”.

20 (b) **ELIMINATION OF DEADWOOD.**—Section 319C–
21 1(h) of the Public Health Service Act (42 U.S.C. 247d–
22 3a(h)) is amended—

23 (1) by striking paragraphs (4) and (5); and

24 (2) by redesignating paragraphs (6) and (7) as
25 paragraphs (4) and (5).

1 **SEC. 302. FACILITIES AND CAPACITIES OF THE CENTERS**
2 **FOR DISEASE CONTROL AND PREVENTION TO**
3 **COMBAT PUBLIC HEALTH SECURITY**
4 **THREATS.**

5 (a) STUDY.—Section 319D(a)(4) of the Public
6 Health Service Act (42 U.S.C. 247d–4(a)(4)) is amended
7 by striking “Not later than June 1, 2022, the Comptroller
8 General of the United States shall conduct a study on
9 Federal spending in fiscal years 2013 through 2018” and
10 inserting “Not later than June 1, 2027, the Comptroller
11 General of the United States shall conduct a study on
12 Federal spending in fiscal years 2021 through 2026”.

13 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
14 319D(h) of the Public Health Service Act (42 U.S.C.
15 247d–4(h)) is amended—

16 (1) in paragraph (1), by striking “\$25,000,000
17 for each of fiscal years 2022 and 2023” and insert-
18 ing “\$40,000,000 for each of fiscal years 2024
19 through 2028”; and

20 (2) in paragraph (2), by striking “2022 and
21 2023” and inserting “2024 through 2028”.

22 **SEC. 303. MONITORING AND DISTRIBUTION OF CERTAIN**
23 **MEDICAL COUNTERMEASURES.**

24 Section 319A(e) of the Public Health Service Act (42
25 U.S.C. 247d–1(e)) is amended by striking “2019 through
26 2023” and inserting “2024 through 2028”.

1 **SEC. 304. ENHANCED CONTROL OF DANGEROUS BIOLOGI-**
2 **CAL AGENTS AND TOXINS.**

3 Section 351A(m) of the Public Health Service Act
4 (42 U.S.C. 262a(m)) is amended by striking “2027” and
5 inserting “2028”.

6 **SEC. 305. MOSQUITO-BORNE DISEASES.**

7 Section 317S(f) of the Public Health Service Act (42
8 U.S.C. 247b–21(f)) is amended—

9 (1) in paragraph (1), by striking “2019
10 through 2023” and inserting “2024 through 2028”;
11 and

12 (2) by striking paragraph (3).

13 **SEC. 306. EPIDEMIOLOGY-LABORATORY CAPACITY.**

14 Section 2821(b) (42 U.S.C. 300hh–31(b)) is amend-
15 ed by striking “2019 through 2023” and inserting “2024
16 through 2028”.

17 **SEC. 307. SUPPORTING PUBLIC HEALTH DATA AVAIL-**
18 **ABILITY AND ACCESS.**

19 (a) DESIGNATION OF PUBLIC HEALTH DATA STAND-
20 ARDS.—Section 2823(a)(2) of the Public Health Service
21 Act (42 U.S.C. 300hh–33(a)(2)) is amended by adding at
22 the end the following:

23 “(D) SELECTION OF DATA AND TECH-
24 NOLOGY STANDARDS.—The standards des-
25 igned as described in subparagraph (A) may
26 include standards to improve—

1 “(i) the exchange of electronic health
2 information for—

3 “(I) electronic case reporting;

4 “(II) syndromic surveillance;

5 “(III) reporting of vital statistics;

6 and

7 “(IV) reporting test orders and
8 results electronically, including from
9 laboratories;

10 “(ii) automated electronic reporting to
11 relevant public health data systems of the
12 Centers for Disease Control and Preven-
13 tion; and

14 “(iii) such other uses as the Secretary
15 determines appropriate.

16 “(E) CONSIDERATIONS.—Standards des-
17 igned under this paragraph shall include
18 standards and implementation specifications
19 necessary to ensure the appropriate capture, ex-
20 change, access, and use of information regard-
21 ing race, ethnicity, sex (including sexual ori-
22 entation and gender identity), disability status,
23 veteran status, housing status, age, functional
24 status, and other elements.”.

1 (b) IMPROVING INFORMATION SHARING AND AVAIL-
2 ABILITY OF PUBLIC HEALTH DATA.—Section 310B of the
3 Public Health Service Act (42 U.S.C. 242u) is amended
4 to read as follows:

5 **“SEC. 310B. IMPROVING INFORMATION SHARING AND**
6 **AVAILABILITY OF PUBLIC HEALTH DATA.**

7 “(a) IN GENERAL.—The Secretary acting through
8 the Director of the Centers for Disease Control and Pre-
9 vention (in this section referred to as the ‘Secretary’) may
10 require the reporting of public health and health care data
11 and information to the Centers for Disease Control and
12 Prevention by—

13 “(1) health care providers and facilities, includ-
14 ing pharmacies;

15 “(2) public health, clinical, and other labora-
16 tories and diagnostic testing entities;

17 “(3) State, local, and Tribal health depart-
18 ments; and

19 “(4) other entities, as determined appropriate
20 by the Secretary.

21 “(b) CONTENT, FORM, MANNER, AND FRE-
22 QUENCY.—

23 “(1) COLLABORATION.—The Secretary shall
24 collaborate with representatives of State, local, and
25 Tribal health departments and other entities on de-

1 termining the content, form, manner, and frequency
2 of the reporting of public health and health care
3 data and information required pursuant to sub-
4 section (a).

5 “(2) SIMULTANEOUS REPORTING.—In deter-
6 mining the content, form, manner, and frequency of
7 the reporting of public health and health care data
8 and information pursuant to subsection (a), where a
9 disease, condition, or related event is reportable
10 under applicable State or local law, the Secretary
11 shall require the data and information to be reported
12 first or simultaneously to the appropriate State or
13 local jurisdiction.

14 “(3) ALIGNMENT WITH STANDARDS AND IM-
15 PLEMENTATION SPECIFICATIONS.—The content,
16 form, manner, and frequency requirements required
17 pursuant to this section shall align with the stand-
18 ards and implementation specifications adopted by
19 the Secretary under section 3004, where applicable.

20 “(4) REASONABLE EFFORTS TO LIMIT REPORT-
21 ING.—The Secretary shall make reasonable efforts
22 to limit the public health and health care data and
23 information required to be reported under this sec-
24 tion to the minimum necessary to accomplish the in-
25 tended public health purpose.

1 “(5) IMPLEMENTATION AND REGULATIONS.—

2 The Secretary—

3 “(A) may promulgate by regulation the
4 content, form, manner, and frequency in which
5 public health and health care data and informa-
6 tion is required to be reported under this sec-
7 tion; and

8 “(B) in the event of a public health emer-
9 gency declared under section 319, or where the
10 Secretary determines there is a significant po-
11 tential for such an emergency to exist, may
12 issue such requirements—

13 “(i) by guidance in accordance with
14 this section; and

15 “(ii) without regard to the procedures
16 otherwise required by section 553 of title
17 5, United States Code.

18 “(c) ENSURING THAT DATA IS ACCESSIBLE IN A
19 TIMELY MANNER TO STATE, LOCAL, AND TRIBAL
20 HEALTH AUTHORITIES.—

21 “(1) COLLABORATION.—The Secretary shall
22 collaborate with representatives of State, local, and
23 Tribal health departments, and entities representing
24 such departments, to ensure that data and informa-
25 tion that is collected by the Centers for Disease Con-

1 trol and Prevention pursuant to this section are ac-
2 cessible, as appropriate, in a timely manner, to
3 State, local, and Tribal health authorities.

4 “(2) RULES OF CONSTRUCTION.—Nothing in
5 this section shall be construed—

6 “(A) to prevent any Federal agency, State,
7 local, or Tribal health department, or other en-
8 tity from collecting data or information under
9 other applicable law; or

10 “(B) to limit the authority of the Centers
11 for Disease Control and Prevention to share
12 public health surveillance data with State, local,
13 or Tribal health authorities.

14 “(3) REASONABLE EFFORTS TO REDUCE RE-
15 PORTING BURDENS AND POTENTIAL DUPLICA-
16 TION.—The Secretary shall make reasonable efforts
17 to collaborate with representatives of Federal agen-
18 cies and State, local, and Tribal health departments
19 to reduce reporting burdens and potential duplica-
20 tion of reporting requirements. Such efforts may in-
21 clude ensuring simultaneous sharing of data and in-
22 formation described in subsection (b) with State,
23 local, and Tribal public health authorities.

24 “(d) CONFIDENTIALITY AND PROTECTION OF
25 DATA.—Any identifiable, sensitive information reported to

1 the Centers for Disease Control and Prevention pursuant
2 to this section shall not be further disclosed or provided
3 to any other individual or party, including any party in-
4 volved in civil, criminal, or administrative litigation, ex-
5 cept—

6 “(1) as necessary for public health purposes, in-
7 cluding with relevant Federal, State, local, or tribal
8 public health authorities;

9 “(2) as required under section 552a(d)(1) of
10 title 5, United States Code;

11 “(3) as required by applicable Federal laws, ex-
12 cluding instances of disclosure in any Federal, State,
13 or local civil, criminal, administrative, legislative, or
14 other proceeding; or

15 “(4) with the consent of each individual to
16 whom the information pertains.

17 “(e) EXEMPTION OF CERTAIN PUBLIC HEALTH
18 DATA FROM DISCLOSURE.—The Secretary may exempt
19 from disclosure under section 552(b)(3) of title 5, United
20 States Code, public health and health care data and infor-
21 mation collected by the Centers for Disease Control and
22 Prevention pursuant to this section or any other authority
23 under which the Centers collects public health or health
24 care data and information if—

1 “(1) an individual is identified through such
2 data or information; or

3 “(2) there is at least a very small risk, as deter-
4 mined by current scientific practices or statistical
5 methods, that some combination of the data or in-
6 formation, the request for disclosure under such sec-
7 tion 552(b)(3), and other available data sources or
8 the application of technology could be used to de-
9 duce the identity of the individuals to which such
10 data or information pertains.”.

11 (c) PUBLIC HEALTH INFORMATION SHARING AND
12 AVAILABILITY ADVISORY COMMITTEE.—Part A of title III
13 of the Public Health Service Act (42 U.S.C. 241 et seq.)
14 is amended by adding at the end the following:

15 **“SEC. 310C. PUBLIC HEALTH INFORMATION SHARING AND**
16 **AVAILABILITY ADVISORY COMMITTEE.**

17 “(a) ESTABLISHMENT.—The Secretary, acting
18 through the Director of the Centers for Disease Control
19 and Prevention, shall establish an advisory committee, to
20 be known as the Public Health Information Sharing and
21 Availability Advisory Committee, to advise, and make rec-
22 ommendations to, the Director with respect to the imple-
23 mentation of public health and health care data and infor-
24 mation reporting and sharing under section 310B.

1 “(b) MEMBERSHIP.—The membership of the advisory
2 committee established pursuant to this section shall in-
3 clude—

4 “(1) individuals with subject matter expertise
5 or experience in the following areas of public health
6 and health care data and information, including—

7 “(A) State, territorial, local, and Tribal
8 health department data systems or practices;
9 and

10 “(B) health care data;

11 “(2) ex officio members, including from relevant
12 Federal agencies such as the Office of the National
13 Coordinator for Health Information Technology, the
14 Centers for Medicare & Medicaid Services, the Cen-
15 ters for Disease Control and Prevention, and the Of-
16 fice of the Assistant Secretary for Health;

17 “(3) representatives of national organizations,
18 including the Council of State and Territorial Epi-
19 demologists, the Association of Public Health Lab-
20 oratories, the Association of State and Territorial
21 Health Officials, the National Association of County
22 and City Health Officials, and the Big Cities Health
23 Coalition; and

24 “(4) such additional members as the Secretary
25 determines appropriate.

1 “(c) FACA APPLICABILITY.—The advisory com-
2 mittee established pursuant to this section is deemed to
3 be an advisory committee subject to the Federal Advisory
4 Committee Act.”.

5 (d) IMPROVING PUBLIC HEALTH DATA COLLEC-
6 TION.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services (referred to in this subsection as
9 the “Secretary”) shall award grants, contracts, or
10 cooperative agreements to eligible entities for pur-
11 poses of identifying, developing, or disseminating
12 best practices in the collection of electronic health
13 information and the use of designated data stand-
14 ards and implementation specifications—

15 (A) to improve the quality and complete-
16 ness of data, including demographic data, col-
17 lected, accessed, or used for public health pur-
18 poses; and

19 (B) to address health disparities and re-
20 lated health outcomes.

21 (2) ELIGIBLE ENTITIES.—To be eligible to re-
22 ceive an award under this subsection an entity
23 shall—

24 (A) be a health care provider, academic
25 medical center, community-based organization,

1 State, local governmental entity, Indian Tribe
2 or Tribal organization (as such terms are de-
3 fined in section 4 of the Indian Self Determina-
4 tion and Education Assistance Act (25 U.S.C.
5 5304)), Urban Indian organization (as defined
6 in section 4 of the Indian Health Care Improve-
7 ment Act (25 U.S.C. 1603)), or other appro-
8 priate public or private nonprofit entity, or a
9 consortia of any such entities; and

10 (B) submit an application to the Secretary
11 at such time, in such manner, and containing
12 such information as the Secretary may require.

13 (3) ACTIVITIES.—Entities receiving awards
14 under this subsection shall use such award to de-
15 velop and test best practices for training health care
16 providers to use standards and implementation spec-
17 ifications that assist in the capture, access, ex-
18 change, and use of electronic health information, in-
19 cluding demographic information, disability status,
20 veteran status, housing status, functional status,
21 and other data elements. Such activities shall, at a
22 minimum, include—

23 (A) improving, understanding, and using
24 data standards and implementation specifica-
25 tions;

1 (B) developing or identifying methods to
2 improve communication with patients in a cul-
3 turally and linguistically appropriate manner,
4 including to better capture information related
5 to demographics of such individuals;

6 (C) developing methods for accurately cat-
7 egorizing and recording patient responses using
8 available data standards;

9 (D) educating providers regarding the util-
10 ity of such information for public health pur-
11 poses and the importance of accurate collection
12 and recording of such data; and

13 (E) other activities, as the Secretary deter-
14 mines appropriate.

15 (4) REPORTING.—

16 (A) REPORTING BY AWARD RECIPIENTS.—
17 Each recipient of an award under this sub-
18 section shall submit to the Secretary a report
19 on the results of best practices identified, devel-
20 oped, or disseminated through such award.

21 (B) REPORT TO CONGRESS.—Not later
22 than 1 year after the completion of the program
23 under this subsection, the Secretary shall sub-
24 mit a report to Congress on the success of the
25 best practices developed under such program,

1 opportunities for further dissemination of such
2 best practices, and recommendations for im-
3 proving the capture, access, exchange, and use
4 of information to improve public health and re-
5 duce health disparities.

6 (5) NONDUPLICATION OF EFFORTS.—The Sec-
7 retary shall ensure that the activities and programs
8 carried out under this subsection are free of unnec-
9 essary duplication of effort.

10 (6) AUTHORIZATION OF APPROPRIATIONS.—
11 There is authorized to be appropriated \$10,000,000
12 for each of fiscal years 2024 through 2026 to carry
13 out this subsection.

14 (e) INFORMATION COLLECTION.—Section 319D(a) of
15 the Public Health Service Act (42 U.S.C. 247d–4(a)) is
16 amended by adding at the end the following:

17 “(5) INFORMATION COLLECTION.—Subchapter
18 I of chapter 35 of title 44, United States Code, shall
19 not apply to information collection by the Centers
20 for Disease Control and Prevention, including the
21 Agency for Toxic Substances and Disease Registry,
22 that are part of investigations, research, surveil-
23 lance, or evaluations undertaken for public health
24 purposes under any available authority.”.

1 **TITLE IV—ENSURING WORK-**
2 **FORCE TO PREPARE FOR AND**
3 **RESPOND TO PUBLIC HEALTH**
4 **SECURITY THREATS**

5 **SEC. 401. TEMPORARY REASSIGNMENT OF STATE AND**
6 **LOCAL PERSONNEL DURING A PUBLIC**
7 **HEALTH EMERGENCY.**

8 (a) REPORT TO CONGRESS.—Section 319(e)(6) of the
9 Public Health Service Act (42 U.S.C. 247d(e)(6)) is
10 amended by striking “Not later than 4 years after the date
11 of enactment of the Pandemic and All-Hazards Prepared-
12 ness Reauthorization Act of 2013, the Comptroller Gen-
13 eral of the United States shall” and inserting “Not later
14 than 4 years after the date of enactment of the Protecting
15 PAHPA Act of 2023, the Comptroller General of the
16 United States shall”.

17 (b) SUNSET.—Section 319(e)(8) of the Public Health
18 Service Act (42 U.S.C. 247d(e)(8)) is amended by striking
19 “2023” and inserting “2028”.

20 **SEC. 402. EPIDEMIC INTELLIGENCE SERVICE.**

21 Section 317F(c)(2) of the Public Health Service Act
22 (42 U.S.C. 247b–7(c)(2)) is amended by striking “2019
23 through 2023” and inserting “2024 through 2028”.

1 **TITLE V—ADDRESSING DRUG**
2 **AND SUPPLY CHAIN SHORTAGES**
3 **Subtitle A—Ensuring Access to**
4 **Lifesaving Drugs**

5 **SEC. 501. EXTENDED EXPIRATION DATES FOR LIFE-SAVING**
6 **DRUGS.**

7 (a) IN GENERAL.—The Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 301 et seq.) is amended by in-
9 serting after section 506L of such Act (21 U.S.C. 356l)
10 the following new section:

11 **“SEC. 506M. EXTENDED EXPIRATION DATES FOR LIFE-SAV-**
12 **ING DRUGS.**

13 “(a) IN GENERAL.—A manufacturer of a life-saving
14 drug shall—

15 “(1) submit to the Secretary data and informa-
16 tion as required by subsection (b)(1);

17 “(2) conduct and submit the results, data, and
18 information generated by any studies required under
19 subsection (b)(2); and

20 “(3) make any labeling change described in
21 subsection (c) by the date specified by the Secretary
22 pursuant to such subsection.

23 “(b) DATA AND INFORMATION.—

24 “(1) IN GENERAL.—The Secretary may issue
25 an order requiring the manufacturer of a life-saving

1 drug to submit, in such manner as the Secretary
2 may prescribe, data and information from any stage
3 of development of the drug that are adequate to as-
4 sess the stability of the drug to determine the long-
5 est supported expiration date.

6 “(2) LACK OF DATA AND INFORMATION.—If the
7 data and information required pursuant to an order
8 issued under paragraph (1) are not available or are
9 insufficient, as determined by the Secretary, the Sec-
10 retary may issue an order requiring the manufac-
11 turer of the drug—

12 “(A) to conduct studies, which may be a
13 continuation of ongoing studies, to provide data
14 and information adequate to assess the stability
15 of the drug and to determine the longest sup-
16 ported expiration date; and

17 “(B) to submit such data and information
18 to the Secretary in such manner as the Sec-
19 retary may prescribe in the order.

20 “(c) LABELING.—The Secretary may issue an order
21 requiring the manufacturer of a life-saving drug, by a date
22 determined by the Secretary in consultation with the spon-
23 sor of the drug, to make any labeling change regarding
24 the expiration date or storage and handling of the drug
25 that the Secretary determines to be appropriate based on

1 the data and information required to be submitted under
2 this section or any other data and information available
3 to the Secretary.

4 “(d) DEFINITIONS.—In this section:

5 “(1) LIFE-SAVING DRUG.—The term ‘life-saving
6 drug’ means a drug, that is—

7 “(A)(i) a medical countermeasure; or

8 “(ii) on the drug shortage list under sec-
9 tion 506E or determined by the Secretary to be
10 at risk of shortage; and

11 “(B)(i) life-supporting;

12 “(ii) life-sustaining; or

13 “(iii) intended for use in the prevention or
14 treatment of a debilitating disease or condition
15 in humans or animals, including any such drug
16 used in emergency medical care or during sur-
17 gery or any such drug that is critical to the
18 public health during a public health emergency
19 declared by the Secretary under section 319 of
20 the Public Health Service Act.

21 “(2) MEDICAL COUNTERMEASURE.—The term
22 ‘medical countermeasure’ means a countermeasure
23 as defined in section 565(a).

24 “(e) CONFIDENTIALITY.—Nothing in this section
25 shall be construed as authorizing the Secretary to disclose

1 any information that is a trade secret or confidential infor-
2 mation subject to section 552(b)(4) of title 5, United
3 States Code, or section 1905 of title 18, United States
4 Code.”.

5 (b) PROHIBITED ACT.—Section 301 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
7 amended by section 3503(a)(1)(A) of division FF of Pub-
8 lic Law 117–328, is amended by inserting at the end the
9 following new subsection:

10 “(jjj) The failure to comply with any order issued
11 under section 506M.”.

12 (c) PENALTIES.—Subsection (b) of section 303 of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)
14 is amended by inserting at the end the following:

15 “(9) If a manufacturer of a life-saving drug fails to
16 submit data and information as required under section
17 506M(b)(1), fails to conduct or submit the data and infor-
18 mation generated by studies as required under section
19 506M(b)(2), or fails to make a labeling change as required
20 under section 506M(c), such manufacturer shall be subject
21 to a civil penalty of not more than \$10,000 for the first
22 day on which the violation occurs and not more than
23 \$10,000 for each subsequent day on which the violation
24 is not corrected.”.

1 **Subtitle B—Drug Origin**
2 **Transparency**

3 **SEC. 511. ENHANCED DRUG MANUFACTURING AMOUNT IN-**
4 **FORMATION REPORTING.**

5 (a) IN GENERAL.—Section 510(j)(3) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)) is
7 amended—

8 (1) in subparagraph (A), by adding “or (2)”
9 after “paragraph (1)”; and

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

11 “(C) Each report submitted pursuant to sub-
12 paragraph (A) with respect to a drug shall—

13 “(i) include additional information as may
14 be specified by the Secretary in regulation or
15 guidance regarding the supply chain for such
16 drug, such as—

17 “(I) the identity of the respective sup-
18 pliers of each active pharmaceutical ingre-
19 dient, active pharmaceutical ingredient in-
20 termediate, and in-process material used in
21 such manufacture, preparation, propaga-
22 tion, compounding, or processing of the
23 drug; and

24 “(II) the respective amounts of such
25 drug that were manufactured, prepared,

1 propagated, compounded, or processed
2 using an active pharmaceutical ingredient,
3 active pharmaceutical ingredient inter-
4 mediate, and in-process material from each
5 such identified supplier; and

6 “(ii) be submitted more frequently than
7 annually, in accordance with a reporting sched-
8 ule as may be specified by the Secretary in such
9 regulation or guidance, but not more frequently
10 than 4 times per year.

11 “(D) Any additional information specified in
12 regulation or guidance pursuant to subparagraph
13 (C) shall be a required element of reports under this
14 paragraph not earlier than 6 months after the date
15 on which such regulation or guidance is issued in
16 final form (and in no event shall the absence of any
17 regulation or guidance issued under subparagraph
18 (C) affect the requirement to report as described in
19 subparagraph (A)).”.

20 (b) CONFORMING AMENDMENT.—Section
21 510(j)(3)(B) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 510(j)(3)(B)) is amended by striking “sub-
23 paragraph (A)” and inserting “this paragraph”.

1 **SEC. 512. REQUIRE DRUG LABELING TO INCLUDE ORIGI-**
2 **NAL MANUFACTURER AND SUPPLY CHAIN IN-**
3 **FORMATION.**

4 Section 502 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 352) is amended—

6 (1) in paragraph (b)—

7 (A) by striking “(b) If in a package” and
8 inserting “(b)(1) If in a package”;

9 (B) by striking “a label containing (1) the
10 name and place” and inserting “a label con-
11 taining—

12 “(A) the name and place”;

13 (C) by striking “or distributor; and (2) an
14 accurate statement” and inserting “or dis-
15 tributor; and

16 “(B) an accurate statement”;

17 (D) by striking “under clause (2) of this
18 paragraph” and inserting “under this clause”;
19 and

20 (E) by inserting at the end the following:

21 “(2)(A) Subject to clause (C), if it is a drug,
22 including an active pharmaceutical ingredient, unless
23 it bears a label containing the name and place of
24 business, and unique facility identifier of the original
25 manufacturer of such drug or active pharmaceutical
26 ingredient, except that the Secretary may provide,

1 by regulation, for reasonable variations in the imple-
2 mentation of such labeling requirements.

3 “(B) Subject to clause (C), if it is a drug that
4 is an active pharmaceutical ingredient, unless any
5 accompanying certificate of analysis contains the
6 name and place of business, and unique facility iden-
7 tifier of the original manufacturer of the active
8 pharmaceutical ingredient.

9 “(C) The Secretary may provide, by regulation,
10 for reasonable variations in the implementation of
11 labeling requirements specified in this subpara-
12 graph.”; and

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

15 “(d)(1) Subject to subparagraph (2), if it is a drug,
16 including an active pharmaceutical ingredient, unless it
17 bears labeling containing the name and place of business
18 of—

19 “(A) the original manufacturer of each active
20 pharmaceutical ingredient;

21 “(B) each manufacturer, if different from the
22 original manufacturer; and

23 “(C) the packer or distributor, if any.

24 “(2) The Secretary may provide, by regulation, for
25 reasonable variations or an alternative placement for the

1 labeling requirements specified in subparagraph (1), in-
2 cluding by electronic means.”.

3 **Subtitle C—Medical Device** 4 **Shortage Reduction**

5 **SEC. 521. CLARIFYING DEVICE SHORTAGE NOTIFICATIONS.**

6 Section 506J(a) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 356j(a)) is amended—

8 (1) in paragraph (2), by striking “during, or in
9 advance of, a public health emergency”; and

10 (2) in the matter following paragraph (2), by
11 striking “, during, or in advance of, a public health
12 emergency declared by the Secretary under section
13 319 of the Public Health Service Act,”.

14 **SEC. 522. SUPPLY CHAIN RISK MANAGEMENT.**

15 (a) Section 506J of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 356j) is amended by striking
17 subsection (h) and inserting the following:

18 “(h) **RISK MANAGEMENT PLANS.**—Each manufac-
19 turer of a device described in subsection (a) shall develop,
20 maintain, and, as appropriate, implement a risk manage-
21 ment plan that identifies and evaluates risks to the supply
22 of the device, as applicable, for each establishment in
23 which such device is manufactured. Such risk management
24 plan—

1 “(1) may identify and evaluate risks to the sup-
2 ply of more than 1 device, or device category, manu-
3 factured at the same establishment; and

4 “(2) shall be subject to inspection and copying
5 by the Secretary pursuant to section 704 or at the
6 request of the Secretary.”.

7 (b) CONFORMING AMENDMENT.—Section 506J(f) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 356j(f)) is amended by striking “or (h)” after “subsection
10 (a)”.

11 **SEC. 523. CLARIFYING VOLUNTARY NOTIFICATIONS.**

12 Section 506J(i) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 356j(i)) is amended by adding at
14 the end the following: “Nothing in this section shall be
15 construed to limit the authority of the Secretary to request
16 that a manufacturer (or other person involved in the de-
17 vice supply chain) provide, on a voluntary basis, informa-
18 tion to the Secretary or the authority of the Secretary to
19 receive such information.”.

1 **Subtitle D—Drug Shortage**
2 **Prevention**

3 **SEC. 531. IMPROVING NOTIFICATION PROCEDURES IN**
4 **CASE OF INCREASED DEMAND FOR CRITICAL**
5 **ESSENTIAL MEDICINES.**

6 (a) IN GENERAL.—Section 506C of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amend-
8 ed—

9 (1) in the section heading, by striking “**DIS-**
10 **CONTINUANCE OR INTERRUPTION IN THE PRO-**
11 **DUCTION OF LIFE-SAVING DRUGS**” and inserting
12 “**NOTIFICATION OF ISSUES AFFECTING DOMES-**
13 **TIC SUPPLY OF CRITICAL ESSENTIAL MEDI-**
14 **CINES**”;

15 (2) by striking subsections (a), (b), and (c), and
16 inserting the following:

17 “(a) NOTIFICATION REQUIRED.—

18 “(1) IN GENERAL.—A manufacturer of a crit-
19 ical essential medicine shall notify the Secretary, in
20 accordance with subsection (b), of—

21 “(A)(i) a permanent discontinuance in the
22 manufacture of the drug or an interruption of
23 the manufacture of the drug that is likely to
24 lead to a meaningful disruption in the supply of
25 such drug in the United States;

1 “(ii) a permanent discontinuance in the
2 manufacture of an active pharmaceutical ingre-
3 dient, an excipient, or any other input in the
4 final dosage form of such drug or an interrup-
5 tion in the manufacture of the active pharma-
6 ceutical ingredient, an excipient, or any other
7 input in the final dosage form of such drug of
8 such drug that is likely to lead to a meaningful
9 disruption in the supply of the active pharma-
10 ceutical ingredient of such drug;

11 “(iii) an increased demand (other than an
12 anticipated seasonal surge) for such drug or an
13 active pharmaceutical ingredient, an excipient,
14 or any other input in the final dosage form of
15 such drug that is likely to lead to a shortage of
16 the drug or the active pharmaceutical ingre-
17 dient, an excipient, or any other input in the
18 final dosage form of such drug; and

19 “(B) the reasons for such discontinuance,
20 interruption, or increased demand.

21 “(2) CONTENTS.—Notification under this sub-
22 section with respect to a critical essential medicine
23 shall include—

24 “(A) with respect to the reasons for the
25 discontinuation, interruption, or increased de-

1 mand referred to in paragraph (1)(C), if an ac-
2 tive pharmaceutical ingredient, an excipient, or
3 any other input in the final dosage form of such
4 drug is a reason for, or risk factor in, such dis-
5 continuation, interruption, or increased de-
6 mand, the source of the active pharmaceutical
7 ingredient, excipient, or other input and any al-
8 ternative sources for the an active pharma-
9 ceutical ingredient, an excipient, or any other
10 input by the manufacturer;

11 “(B) whether any associated device used
12 for preparation or administration included in
13 the drug is a reason for, or a risk factor in,
14 such discontinuation, interruption, or increased
15 demand;

16 “(C) the expected duration of the interrup-
17 tion or increased demand; and

18 “(D) such other information as the Sec-
19 retary may require.

20 “(b) TIMING.—

21 “(1) IN GENERAL.—A notice required under
22 subsection (a) shall be submitted to the Secretary—

23 “(A) at least 6 months prior to the date of
24 the discontinuance or interruption;

1 “(B) in the case of such a notice with re-
2 spect to increased demand for a critical essen-
3 tial medicine, not later than 30 days after the
4 submission of the initial notification under
5 paragraph (2); or

6 “(C) if compliance with subparagraph (A)
7 or (B) is not possible, as soon as practicable.

8 “(2) INITIAL NOTIFICATION WITH RESPECT TO
9 INCREASED DEMAND.—In the case a notification re-
10 quired under subsection (a) with respect to increased
11 demand for a critical essential medicine, the manu-
12 facturer of the drug involved shall submit to the
13 Secretary an initial notification not later than 48
14 hours after the date on which there has been in-
15 creased demand for the critical essential medicine
16 for a period of at least 6 consecutive weeks.

17 “(c) DISTRIBUTION.—To the maximum extent prac-
18 ticable, the Secretary shall distribute, through such means
19 as the Secretary deems appropriate, information on the
20 discontinuance or interruption of the manufacture of, or
21 the increased demand for, critical essential medicines to
22 appropriate organizations, including physician, health pro-
23 vider, and patient organizations, as described in section
24 506E.”;

1 (3) in subsection (g), in the matter preceding
2 paragraph (1), by striking “drug described in sub-
3 section (a)” and inserting “critical essential medi-
4 cine”; and

5 (4) in subsection (j), by striking “drug de-
6 scribed in subsection (a)” and inserting “critical es-
7 sential medicine”.

8 (b) APPLICATION TO NONPRESCRIPTION DRUGS.—
9 Section 506C(h) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 356c(h)) is amended—

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

13 (2) in paragraph (2)(A) (as so redesignated), by
14 striking “and that is subject to section 503(b)(1)”
15 and inserting “, including a drug that is not subject
16 to section 503(b)(1)”; and

17 (3) by inserting before paragraph (2) (as so re-
18 designated) the following:

19 “(1) the term ‘critical essential medicine’ means
20 a drug that—

21 “(A) is—

22 “(i) life-supporting;

23 “(ii) life-sustaining; or

24 “(iii) intended for use in the preven-
25 tion or treatment of a debilitating disease

1 or condition, including any such drug used
2 in emergency medical care or during sur-
3 gery or any such drug that is critical to
4 the public health during a public health
5 emergency declared by the Secretary under
6 section 319 of the Public Health Service
7 Act; and

8 “(B) is not a radio pharmaceutical drug
9 product or any other product as designated by
10 the Secretary;”.

11 (c) REGULATIONS.—Not later than 18 months after
12 the date of the enactment of this Act, the Secretary of
13 Health and Human Services shall issue final regulations
14 to implement the amendments made by subsections (a)
15 and (b).

16 (d) GUIDANCE.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services, acting through the Commissioner
19 of Food and Drugs, shall issue guidance on the re-
20 quirements for notifications required to be submitted
21 under section 506C of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 356c), as amended by sub-
23 sections (a) and (b), with respect to increased de-
24 mand for critical essential medicines (as defined in

1 such section 506C). Such guidance shall specifically
2 address—

3 (A) the ways in which manufacturers of
4 critical essential medicines can improve demand
5 predictability;

6 (B) what information manufacturers of
7 critical essential medicines should send to the
8 Secretary; and

9 (C) what communications from the manu-
10 facturer the Secretary would request with re-
11 spect to increases in demand following such no-
12 tifications.

13 (2) CONSULTATION.—In developing such guid-
14 ance, the Secretary shall consult with relevant stake-
15 holders, including manufacturers of critical essential
16 medicines and local, State, or Federal public health
17 officials.

18 (3) TIMING.—The Secretary of Health and
19 Human Services, acting through the Commissioner
20 of Food and Drugs, shall issue—

21 (A) draft guidance under paragraph (1)
22 not later than 120 days after the date of the
23 enactment of this Act; and

1 (B) final guidance under such paragraph
2 not later than 180 days after the date of the
3 enactment of this Act.

4 **Subtitle E—Protecting Americans**
5 **From Unsafe Drugs**

6 **SEC. 541. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
7 **OF DRUGS.**

8 (a) ORDER TO CEASE DISTRIBUTION AND RE-
9 CALL.—Section 569D of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 360bbb–8d) is amended—

11 (1) in the section heading, by striking “**CON-**
12 **TROLLED SUBSTANCES**” and inserting “**DRUGS**”;

13 (2) by striking “controlled substance” each
14 place such term appears and inserting “drug”;

15 (3) in subsection (b)—

16 (A) by striking “controlled substances”
17 and inserting “drugs”; and

18 (B) by inserting “of subsection (a)” after
19 “an order pursuant to paragraph (1) or an
20 amended order pursuant to subparagraph (B)
21 or (C) of paragraph (3)”; and

22 (4) in subsection (c), by striking “or an official
23 senior to such Director” and inserting “or the Direc-
24 tor of the Center for Biologics Evaluation and Re-

1 search (or an official senior to either such Direc-
2 tor)”.

3 (b) IMPORTS AND EXPORTS.—Section 801(a) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 381(a)), as amended by section 3503(a)(4)(C) of division
6 FF of Public Law 117–328, is amended by striking “is
7 a controlled substance subject to an order under section
8 569D” and inserting “is a drug subject to an order under
9 section 569D”.

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