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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

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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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Protecting Pandemic and All-Hazards Preparedness Act of 2023'' or the ''Protecting PAHPA Act of 2023''.

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

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

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

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

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

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

"(11) CYBERSECURITY RESILIENCY OF HEALTH CARE DELIVERY SYSTEMS.—Strengthening the ability of States, local communities, Tribal communities, and territorial entities to protect against, mitigate, or otherwise address the impact of cybersecurity risks or cybersecurity attacks that affect public health through mechanisms (including awards of grants or cooperative agreements under section 319C–2) that encourage hospitals and other facilities involved in the delivery of health care items and services to use recognized security practices meeting or exceeding the approaches promulgated under section 405(d) of the Cybersecurity Act of 2015.".

SEC. 102. PROTECTION OF NATIONAL SECURITY FROM THREATS.

Section 2811(f)(2)(A) of the Public Health Service Act (42 U.S.C. 300hh–10(f)(2)(A)) is amended by striking ''$250,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$327,991,000 for each of fiscal years 2024 through 2028''.

SEC. 103. PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.

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

(1) by striking ''is authorized to be appropriated'' and inserting ''are authorized to be appropriated''; and

(2) by inserting '' and $500,000,000 for each of fiscal years 2024 through 2028'' before the period at the end.

(b) SUNSET.—Section 319C–2(j)(1)(B)(iii) of the Public Health Service Act (42 U.S.C. 247d–3b(j)(1)(B)(iii)) is amended by striking ''2023'' and inserting ''2028''.

SEC. 104. GUIDELINES FOR REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

(a) GUIDELINES.—Section 319C–3(b)(3) of the Public Health Service Act (42 U.S.C. 247d–3c(b)(3)) is amended by striking ''the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (including any amendments made by such Act)'' and inserting ''the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, the PREVENT Pandemics Act (title II of division FF of Public Law 117–328), and the Protecting Pandemic and All-Hazards Preparedness Act of 2023''.

(b) DEMONSTRATION PROJECT FOR REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE SYSTEMS.—Section 319C–3(e)(2) of the Public Health Service Act (42 U.S.C. 247d–3c(e)(2)) is amended by striking ''2023'' and inserting ''2028''.

SEC. 105. STRATEGIC NATIONAL STOCKPILE.

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

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

facturers or distributors of medical products,'' the following: ''as well as clinical laboratories,''; and

(2) in clause (ii), by striking ''domestic manufacturing capacity'' and inserting ''domestic manufacturing and laboratory capacity''.

(b) AUTHORIZATION OF APPROPRIATIONS.—

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

(A) in paragraph (1), by striking ''$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023'' and inserting ''$1,963,000,000 for each of fiscal years 2024 through 2028'';

(B) by striking paragraph (2); and

(C) by striking ''AUTHORIZATION OF APPROPRIATIONS'' and all that follows through ''For the purpose of carrying out subsection (a), there are authorized to be appropriated'' and inserting ''AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there is authorized to be appropriated''.

(2) PILOT PROGRAM TO SUPPORT STATE MEDICAL STOCKPILES.—Section 319F–2(i)(9) of the Public Health Service Act (42 U.S.C. 247d–6b(i)(9)) is amended by striking ''2024'' and inserting ''2028''.

SEC. 106. DIAGNOSTIC TESTING PREPAREDNESS PLAN.

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

''SEC. 319F–6. DIAGNOSTIC TESTING PREPAREDNESS PLAN.

''(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, and in consultation with the heads of relevant Federal agencies, shall develop not later than 1 year after the date of enactment of this section and update not less than every 3 years thereafter a plan for rapid development, authorization, scaling, procurement, and distribution of diagnostics and clinical and diagnostic laboratory testing capacity during a public health emergency declared under section 319.

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

''(1) to facilitate the development and utilization of diagnostics for use with respect to a novel chemical, biological, radiological, or nuclear threat or an emerging infectious disease, including any such

high-throughput laboratory diagnostic, point-of-care diagnostic, or rapid at-home or point-of-use diagnostic; and

''(2) to describe the processes for rapid development, authorization, scaling, procurement, and distribution of diagnostics and clinical and diagnostic laboratory testing capacity.

''(c) PUBLIC-PRIVATE COORDINATION.—

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

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

''(A) government agencies; and

''(B) critical private-sector diagnostic testing stakeholders, including private-sector clinical and diagnostic laboratories, diagnostic manufacturers, health care product distributors, and research laboratories.

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

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

''(e) REPORTS TO CONGRESS.—Not later than 1 year after commencing implementation of the plan under subsection (a) for a public health emergency, the Secretary, acting through the Assistant Secretary for Preparedness and Response, shall submit to the Congress a report evaluating the effectiveness of activities implemented under the plan.''.

SEC. 107. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

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

(1) in subparagraph (D)—

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

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

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

''(iii) the identification and development of platform manufacturing technologies needed for advanced development

and manufacturing of medical countermeasures for viral families which have significant potential to cause a pandemic;

"(iv) advanced research and development of flexible medical countermeasures against priority respiratory virus families and other respiratory viral pathogens with a significant potential to cause a pandemic, with both pathogen-specific and pathogen-agnostic approaches; and"; and

(2) in subparagraph (F)—

(A) in clause (ii), by striking "; and" at the end and inserting a semicolon;

(B) in clause (iii), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(iv) priority virus families and other viral pathogens with a significant potential to cause a pandemic.".

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

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

SEC. 108. ENSURING COLLABORATION AND COORDINATION IN MEDICAL COUNTERMEASURE DEVELOPMENT.

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

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

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

(1) the Supply Chain Control Tower Program (in this section referred to as the ''SCCT Program'') under the Administration for Strategic Preparedness and Response of the Department of Health and Human Services; and

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

(A) to create supply chain visibility into inventory, capacity, and distribution flow of certain products critical to preparedness and response efforts;

(B) to provide insights into demand forecasting and modeling of certain products critical to preparedness and response efforts; or

(C) to inform preparedness and response efforts by targeting distribution and coordinating supply with demand for certain products critical to preparedness and response efforts.

(b) ISSUES.—The review under this section shall include examination of—

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

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

(3) the extent to which such data is provided and shared with end users, including States, localities, Territories, Tribes, and industry partners;

(4) the frequency and cadence of data reporting and sharing by and among States, localities, Territories, Tribes, and industry partners;

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

(6) the process by which States, localities, Territories, Tribes, and industry partners voluntarily choose to participate in the SCCT Program; and

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

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

SEC. 110. REVIEW OF HHS EFFORTS TO ENSURE RAPID PRODUCTION AND DOMESTIC MANUFACTURING CAPACITY OF MEDICAL COUNTERMEASURES.

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

of the United States shall conduct and complete a review examining the efforts of the Secretary of Health and Human Services to ensure that the United States is prepared to rapidly produce qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)) in the event of a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 274d).

(b) CONTENTS.—The review conducted under subsection (a) shall include a review of—

(1) the efforts described in such subsection, including the Secretary's efforts to transition from the Centers for Innovation and Advanced Drug Manufacturing program to any new efforts, including the National Biopharmaceutical Manufacturing Partnership and Industrial Base Expansion Connect;

(2) the progress made toward the implementation of such efforts; and

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

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

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

(1) the results of the review; and

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

SEC. 111. CRISIS STANDARDS OF CARE.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on how to develop or modify State and local crisis standards of care for use during an emergency period (as defined in section 1135(g)(1) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)) so as to bring such standards of care into compliance with the nondiscrimination requirements of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794).

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.

(a) IN GENERAL.—Section 319I(a) of the Public Health Service Act (42 U.S.C. 247d–7b) is amended by striking ''Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall link existing State verification systems to maintain'' and inserting ''The Secretary shall continue to maintain''.

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

SEC. 202. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS.

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

SEC. 203. NATIONAL ADVISORY COMMITTEES ON DISASTERS.

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

''(g) SUNSET.—

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

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

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

(1) in subsection (d)—

(A) in paragraph (1), by striking ''in consultation with such other heads of agencies as appropriate, shall appoint not more than 17 members'' and inserting ''in consultation with such other Secretaries as may be appropriate, shall appoint not more than 23 members'';

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

(C) by amending paragraph (3), as so redesignated—

(i) in the paragraph heading, by striking ''REQUIRED MEMBERS'' and inserting ''REQUIRED FEDERAL MEMBERS'';

(ii) in the matter preceding subparagraph (A), by striking ''and non-Federal members,'';

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

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

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

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

''(A) at least 4 non-Federal health care providers with expertise in geriatric medical disaster planning, preparedness, response, or recovery;

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

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

''(C) at least 4 non-Federal professionals with training in gerontology, including social workers, scientists, human services specialists, or other non-medical professionals, with experience in disaster planning, preparedness, response, or recovery among other adults.''; and

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

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

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

(2) in subsection (g)—

(A) in paragraph (1), by striking ''2023'' and inserting ''2028''; and

(B) in paragraph (2), by striking ''2022'' and inserting ''2027''.

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

(1) by redesignating subsections (c) through (g) as subsections (d) through (h), respectively;

(2) by inserting after subsection (b) the following new subsection:

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

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

(A) in paragraph (1), by striking ''in consultation with such other heads of agencies and departments as appropriate, shall appoint not more than 17 members'' and inserting ''in consultation with such other Secretaries as may be

appropriate, shall appoint not more than 23 members'';

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

(C) by amending paragraph (3), as redesignated—

(i) in the paragraph heading, by striking ''REQUIRED MEMBERS'' and inserting ''REQUIRED FEDERAL MEMBERS'';

(ii) in the matter preceding subparagraph (A), by striking ''and non-Federal members,'';

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

''(K) Representatives of such other Federal agencies as the Secretary determines necessary to fulfill the duties of the Advisory Committee.''; and

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

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

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

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

"(A) at least 4 non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery;

"(B) at least 3 representatives from State, local, Tribal, or territorial agencies with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities; and

"(C) at least 4 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities."; and

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

"(4) TERM OF APPOINTMENT.—Each member of the Advisory Committee appointed under paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the Advisory Committee appointees serving on the date of enactment of the Preparing for All Hazards and Pathogens Reauthorization Act, or appointees who

are initially appointed after such date of enactment, in order to provide for a staggered term of appointment for all members.

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

(4) in subsection (g)—

(A) in paragraph (1), by striking ''2023'' and inserting ''2028''; and

(B) in paragraph (2), by striking ''2022'' and inserting ''2027''.

SEC. 204. NATIONAL DISASTER MEDICAL SYSTEM.

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

(1) by striking ''(A) IN GENERAL.—If the Secretary determines'' and inserting ''If the Secretary determines''; and

(2) by striking subparagraph (B).

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

300hh–11(g)) is amended by striking ''$57,400,000 for each of fiscal years 2019 through 2023'' and inserting ''$96,904,000 for each of fiscal years 2024 through 2028''.

SEC. 205. VOLUNTEER MEDICAL RESERVE CORPS.

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

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

SEC. 301. IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.

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

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

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

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

SEC. 302. FACILITIES AND CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO COMBAT PUBLIC HEALTH SECURITY THREATS.

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

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

(1) in paragraph (1), by striking ''$25,000,000 for each of fiscal years 2022 and 2023'' and inserting ''$40,000,000 for each of fiscal years 2024 through 2028''; and

(2) in paragraph (2), by striking ''2022 and 2023'' and inserting ''2024 through 2028''.

SEC. 303. MONITORING AND DISTRIBUTION OF CERTAIN MEDICAL COUNTERMEASURES.

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

SEC. 304. ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.

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

SEC. 305. MOSQUITO-BORNE DISEASES.

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

(1) in paragraph (1), by striking ''2019 through 2023'' and inserting ''2024 through 2028''; and

(2) by striking paragraph (3).

SEC. 306. EPIDEMIOLOGY-LABORATORY CAPACITY.

Section 2821(b) (42 U.S.C. 300hh–31(b)) is amended by striking ''2019 through 2023'' and inserting ''2024 through 2028''.

SEC. 307. SUPPORTING PUBLIC HEALTH DATA AVAILABILITY AND ACCESS.

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

''(D) SELECTION OF DATA AND TECHNOLOGY STANDARDS.—The standards designated as described in subparagraph (A) may include standards to improve—

''(i) the exchange of electronic health information for—

''(I) electronic case reporting;

''(II) syndromic surveillance;

''(III) reporting of vital statistics; and

''(IV) reporting test orders and results electronically, including from laboratories;

''(ii) automated electronic reporting to relevant public health data systems of the Centers for Disease Control and Prevention; and

''(iii) such other uses as the Secretary determines appropriate.

''(E) CONSIDERATIONS.—Standards designated under this paragraph shall include standards and implementation specifications necessary to ensure the appropriate capture, exchange, access, and use of information regarding race, ethnicity, sex (including sexual orientation and gender identity), disability status, veteran status, housing status, age, functional status, and other elements.''.

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

"SEC. 310B. IMPROVING INFORMATION SHARING AND AVAILABILITY OF PUBLIC HEALTH DATA.

"(a) IN GENERAL.—The Secretary acting through the Director of the Centers for Disease Control and Prevention (in this section referred to as the 'Secretary') may require the reporting of public health and health care data and information to the Centers for Disease Control and Prevention by—

"(1) health care providers and facilities, including pharmacies;

"(2) public health, clinical, and other laboratories and diagnostic testing entities;

"(3) State, local, and Tribal health departments; and

"(4) other entities, as determined appropriate by the Secretary.

"(b) CONTENT, FORM, MANNER, AND FREQUENCY.—

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

termining the content, form, manner, and frequency of the reporting of public health and health care data and information required pursuant to subsection (a).

''(2) SIMULTANEOUS REPORTING.—In determining the content, form, manner, and frequency of the reporting of public health and health care data and information pursuant to subsection (a), where a disease, condition, or related event is reportable under applicable State or local law, the Secretary shall require the data and information to be reported first or simultaneously to the appropriate State or local jurisdiction.

''(3) ALIGNMENT WITH STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—The content, form, manner, and frequency requirements required pursuant to this section shall align with the standards and implementation specifications adopted by the Secretary under section 3004, where applicable.

''(4) REASONABLE EFFORTS TO LIMIT REPORTING.—The Secretary shall make reasonable efforts to limit the public health and health care data and information required to be reported under this section to the minimum necessary to accomplish the intended public health purpose.

"(5) IMPLEMENTATION AND REGULATIONS.—The Secretary—

"(A) may promulgate by regulation the content, form, manner, and frequency in which public health and health care data and information is required to be reported under this section; and

"(B) in the event of a public health emergency declared under section 319, or where the Secretary determines there is a significant potential for such an emergency to exist, may issue such requirements—

"(i) by guidance in accordance with this section; and

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

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

"(1) COLLABORATION.—The Secretary shall collaborate with representatives of State, local, and Tribal health departments, and entities representing such departments, to ensure that data and information that is collected by the Centers for Disease Con-

trol and Prevention pursuant to this section are accessible, as appropriate, in a timely manner, to State, local, and Tribal health authorities.

"(2) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

"(A) to prevent any Federal agency, State, local, or Tribal health department, or other entity from collecting data or information under other applicable law; or

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

"(3) REASONABLE EFFORTS TO REDUCE REPORTING BURDENS AND POTENTIAL DUPLICATION.—The Secretary shall make reasonable efforts to collaborate with representatives of Federal agencies and State, local, and Tribal health departments to reduce reporting burdens and potential duplication of reporting requirements. Such efforts may include ensuring simultaneous sharing of data and information described in subsection (b) with State, local, and Tribal public health authorities.

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

the Centers for Disease Control and Prevention pursuant to this section shall not be further disclosed or provided to any other individual or party, including any party involved in civil, criminal, or administrative litigation, except—

"(1) as necessary for public health purposes, including with relevant Federal, State, local, or tribal public health authorities;

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

"(3) as required by applicable Federal laws, excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding; or

"(4) with the consent of each individual to whom the information pertains.

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

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

''(2) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the data or information, the request for disclosure under such section 552(b)(3), and other available data sources or the application of technology could be used to deduce the identity of the individuals to which such data or information pertains.''.

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

''SEC. 310C. PUBLIC HEALTH INFORMATION SHARING AND AVAILABILITY ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee, to be known as the Public Health Information Sharing and Availability Advisory Committee, to advise, and make recommendations to, the Director with respect to the implementation of public health and health care data and information reporting and sharing under section 310B.

''(b) MEMBERSHIP.—The membership of the advisory committee established pursuant to this section shall include—

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

''(A) State, territorial, local, and Tribal health department data systems or practices; and

''(B) health care data;

''(2) ex officio members, including from relevant Federal agencies such as the Office of the National Coordinator for Health Information Technology, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office of the Assistant Secretary for Health;

''(3) representatives of national organizations, including the Council of State and Territorial Epidemiologists, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and the Big Cities Health Coalition; and

''(4) such additional members as the Secretary determines appropriate.

''(c) FACA APPLICABILITY.—The advisory committee established pursuant to this section is deemed to be an advisory committee subject to the Federal Advisory Committee Act.''.

(d) IMPROVING PUBLIC HEALTH DATA COLLECTION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall award grants, contracts, or cooperative agreements to eligible entities for purposes of identifying, developing, or disseminating best practices in the collection of electronic health information and the use of designated data standards and implementation specifications—

(A) to improve the quality and completeness of data, including demographic data, collected, accessed, or used for public health purposes; and

(B) to address health disparities and related health outcomes.

(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection an entity shall—

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

State, local governmental entity, Indian Tribe or Tribal organization (as such terms are defined in section 4 of the Indian Self Determination and Education Assistance Act (25 U.S.C. 5304)), Urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)), or other appropriate public or private nonprofit entity, or a consortia of any such entities; and

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

(3) ACTIVITIES.—Entities receiving awards under this subsection shall use such award to develop and test best practices for training health care providers to use standards and implementation specifications that assist in the capture, access, exchange, and use of electronic health information, including demographic information, disability status, veteran status, housing status, functional status, and other data elements. Such activities shall, at a minimum, include—

(A) improving, understanding, and using data standards and implementation specifications;

(B) developing or identifying methods to improve communication with patients in a culturally and linguistically appropriate manner, including to better capture information related to demographics of such individuals;

(C) developing methods for accurately categorizing and recording patient responses using available data standards;

(D) educating providers regarding the utility of such information for public health purposes and the importance of accurate collection and recording of such data; and

(E) other activities, as the Secretary determines appropriate.

(4) REPORTING.—

(A) REPORTING BY AWARD RECIPIENTS.—Each recipient of an award under this subsection shall submit to the Secretary a report on the results of best practices identified, developed, or disseminated through such award.

(B) REPORT TO CONGRESS.—Not later than 1 year after the completion of the program under this subsection, the Secretary shall submit a report to Congress on the success of the best practices developed under such program,

opportunities for further dissemination of such best practices, and recommendations for improving the capture, access, exchange, and use of information to improve public health and reduce health disparities.

(5) NONDUPLICATION OF EFFORTS.—The Secretary shall ensure that the activities and programs carried out under this subsection are free of unnecessary duplication of effort.

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

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

''(5) INFORMATION COLLECTION.—Subchapter I of chapter 35 of title 44, United States Code, shall not apply to information collection by the Centers for Disease Control and Prevention, including the Agency for Toxic Substances and Disease Registry, that are part of investigations, research, surveillance, or evaluations undertaken for public health purposes under any available authority.''.

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.

(a) REPORT TO CONGRESS.—Section 319(e)(6) of the Public Health Service Act (42 U.S.C. 247d(e)(6)) is amended by striking ''Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Comptroller General of the United States shall'' and inserting ''Not later than 4 years after the date of enactment of the Protecting PAHPA Act of 2023, the Comptroller General of the United States shall''.

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

SEC. 402. EPIDEMIC INTELLIGENCE SERVICE.

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

TITLE V—ADDRESSING DRUG AND SUPPLY CHAIN SHORTAGES

Subtitle A—Ensuring Access to Lifesaving Drugs

SEC. 501. EXTENDED EXPIRATION DATES FOR LIFE-SAVING DRUGS.

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

"SEC. 506M. EXTENDED EXPIRATION DATES FOR LIFE-SAVING DRUGS.

"(a) IN GENERAL.—A manufacturer of a life-saving drug shall—

"(1) submit to the Secretary data and information as required by subsection (b)(1);

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

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

"(b) DATA AND INFORMATION.—

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

drug to submit, in such manner as the Secretary may prescribe, data and information from any stage of development of the drug that are adequate to assess the stability of the drug to determine the longest supported expiration date.

''(2) LACK OF DATA AND INFORMATION.—If the data and information required pursuant to an order issued under paragraph (1) are not available or are insufficient, as determined by the Secretary, the Secretary may issue an order requiring the manufacturer of the drug—

''(A) to conduct studies, which may be a continuation of ongoing studies, to provide data and information adequate to assess the stability of the drug and to determine the longest supported expiration date; and

''(B) to submit such data and information to the Secretary in such manner as the Secretary may prescribe in the order.

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

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

''(d) DEFINITIONS.—In this section:

''(1) LIFE-SAVING DRUG.—The term 'life-saving drug' means a drug, that is—

''(A)(i) a medical countermeasure; or

''(ii) on the drug shortage list under section 506E or determined by the Secretary to be at risk of shortage; and

''(B)(i) life-supporting;

''(ii) life-sustaining; or

''(iii) intended for use in the prevention or treatment of a debilitating disease or condition in humans or animals, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.

''(2) MEDICAL COUNTERMEASURE.—The term 'medical countermeasure' means a countermeasure as defined in section 565(a).

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

any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''.

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

''(jjj) The failure to comply with any order issued under section 506M.''.

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

''(9) If a manufacturer of a life-saving drug fails to submit data and information as required under section 506M(b)(1), fails to conduct or submit the data and information generated by studies as required under section 506M(b)(2), or fails to make a labeling change as required under section 506M(c), such manufacturer shall be subject to a civil penalty of not more than $10,000 for the first day on which the violation occurs and not more than $10,000 for each subsequent day on which the violation is not corrected.''.

Subtitle B—Drug Origin Transparency

SEC. 511. ENHANCED DRUG MANUFACTURING AMOUNT INFORMATION REPORTING.

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

(1) in subparagraph (A), by adding ''or (2)'' after ''paragraph (1)''; and

(2) by adding at the end the following:

''(C) Each report submitted pursuant to subparagraph (A) with respect to a drug shall—

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

''(I) the identity of the respective suppliers of each active pharmaceutical ingredient, active pharmaceutical ingredient intermediate, and in-process material used in such manufacture, preparation, propagation, compounding, or processing of the drug; and

''(II) the respective amounts of such drug that were manufactured, prepared,

propagated, compounded, or processed using an active pharmaceutical ingredient, active pharmaceutical ingredient intermediate, and in-process material from each such identified supplier; and

''(ii) be submitted more frequently than annually, in accordance with a reporting schedule as may be specified by the Secretary in such regulation or guidance, but not more frequently than 4 times per year.

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

(b) CONFORMING AMENDMENT.—Section 510(j)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 510(j)(3)(B)) is amended by striking ''subparagraph (A)'' and inserting ''this paragraph''.

SEC. 512. REQUIRE DRUG LABELING TO INCLUDE ORIGINAL MANUFACTURER AND SUPPLY CHAIN INFORMATION.

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

(1) in paragraph (b)—

(A) by striking ''(b) If in a package'' and inserting ''(b)(1) If in a package'';

(B) by striking ''a label containing (1) the name and place'' and inserting ''a label containing—

''(A) the name and place'';

(C) by striking ''or distributor; and (2) an accurate statement'' and inserting ''or distributor; and

''(B) an accurate statement'';

(D) by striking ''under clause (2) of this paragraph'' and inserting ''under this clause''; and

(E) by inserting at the end the following:

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

by regulation, for reasonable variations in the implementation of such labeling requirements.

''(B) Subject to clause (C), if it is a drug that is an active pharmaceutical ingredient, unless any accompanying certificate of analysis contains the name and place of business, and unique facility identifier of the original manufacturer of the active pharmaceutical ingredient.

''(C) The Secretary may provide, by regulation, for reasonable variations in the implementation of labeling requirements specified in this subparagraph.''; and

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

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

''(A) the original manufacturer of each active pharmaceutical ingredient;

''(B) each manufacturer, if different from the original manufacturer; and

''(C) the packer or distributor, if any.

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

labeling requirements specified in subparagraph (1), including by electronic means.''.

Subtitle C—Medical Device Shortage Reduction

SEC. 521. CLARIFYING DEVICE SHORTAGE NOTIFICATIONS.

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

(1) in paragraph (2), by striking ''during, or in advance of, a public health emergency''; and

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

SEC. 522. SUPPLY CHAIN RISK MANAGEMENT.

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

''(h) RISK MANAGEMENT PLANS.—Each manufacturer of a device described in subsection (a) shall develop, maintain, and, as appropriate, implement a risk management plan that identifies and evaluates risks to the supply of the device, as applicable, for each establishment in which such device is manufactured. Such risk management plan—

''(1) may identify and evaluate risks to the supply of more than 1 device, or device category, manufactured at the same establishment; and

''(2) shall be subject to inspection and copying by the Secretary pursuant to section 704 or at the request of the Secretary.''.

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

SEC. 523. CLARIFYING VOLUNTARY NOTIFICATIONS.

Section 506J(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j(i)) is amended by adding at the end the following: ''Nothing in this section shall be construed to limit the authority of the Secretary to request that a manufacturer (or other person involved in the device supply chain) provide, on a voluntary basis, information to the Secretary or the authority of the Secretary to receive such information.''.

Subtitle D—Drug Shortage Prevention

SEC. 531. IMPROVING NOTIFICATION PROCEDURES IN CASE OF INCREASED DEMAND FOR CRITICAL ESSENTIAL MEDICINES.

(a) IN GENERAL.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in the section heading, by striking ''**DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS**'' and inserting ''**NOTIFICATION OF ISSUES AFFECTING DOMESTIC SUPPLY OF CRITICAL ESSENTIAL MEDICINES**'';

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

''(a) NOTIFICATION REQUIRED.—

''(1) IN GENERAL.—A manufacturer of a critical essential medicine shall notify the Secretary, in accordance with subsection (b), of—

''(A)(i) a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of such drug in the United States;

''(ii) a permanent discontinuance in the manufacture of an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug or an interruption in the manufacture of the active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug of such drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of such drug;

''(iii) an increased demand (other than an anticipated seasonal surge) for such drug or an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug that is likely to lead to a shortage of the drug or the active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug; and

''(B) the reasons for such discontinuance, interruption, or increased demand.

''(2) CONTENTS.—Notification under this subsection with respect to a critical essential medicine shall include—

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

mand referred to in paragraph (1)(C), if an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug is a reason for, or risk factor in, such discontinuation, interruption, or increased demand, the source of the active pharmaceutical ingredient, excipient, or other input and any alternative sources for the an active pharmaceutical ingredient, an excipient, or any other input by the manufacturer;

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

"(C) the expected duration of the interruption or increased demand; and

"(D) such other information as the Secretary may require.

"(b) TIMING.—

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

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

"(B) in the case of such a notice with respect to increased demand for a critical essential medicine, not later than 30 days after the submission of the initial notification under paragraph (2); or

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

"(2) INITIAL NOTIFICATION WITH RESPECT TO INCREASED DEMAND.—In the case a notification required under subsection (a) with respect to increased demand for a critical essential medicine, the manufacturer of the drug involved shall submit to the Secretary an initial notification not later than 48 hours after the date on which there has been increased demand for the critical essential medicine for a period of at least 6 consecutive weeks.

"(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the discontinuance or interruption of the manufacture of, or the increased demand for, critical essential medicines to appropriate organizations, including physician, health provider, and patient organizations, as described in section 506E.";

(3) in subsection (g), in the matter preceding paragraph (1), by striking ''drug described in subsection (a)'' and inserting ''critical essential medicine''; and

(4) in subsection (j), by striking ''drug described in subsection (a)'' and inserting ''critical essential medicine''.

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

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

(2) in paragraph (2)(A) (as so redesignated), by striking ''and that is subject to section 503(b)(1)'' and inserting '', including a drug that is not subject to section 503(b)(1)''; and

(3) by inserting before paragraph (2) (as so redesignated) the following:

''(1) the term 'critical essential medicine' means a drug that—

''(A) is—

''(i) life-supporting;

''(ii) life-sustaining; or

''(iii) intended for use in the prevention or treatment of a debilitating disease

or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and

''(B) is not a radio pharmaceutical drug product or any other product as designated by the Secretary;''.

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

(d) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance on the requirements for notifications required to be submitted under section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c), as amended by subsections (a) and (b), with respect to increased demand for critical essential medicines (as defined in

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

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

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

(C) what communications from the manufacturer the Secretary would request with respect to increases in demand following such notifications.

(2) CONSULTATION.—In developing such guidance, the Secretary shall consult with relevant stakeholders, including manufacturers of critical essential medicines and local, State, or Federal public health officials.

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

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

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

Subtitle E—Protecting Americans From Unsafe Drugs

SEC. 541. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF DRUGS.

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

(1) in the section heading, by striking ''**CONTROLLED SUBSTANCES**'' and inserting ''**DRUGS**'';

(2) by striking ''controlled substance'' each place such term appears and inserting ''drug'';

(3) in subsection (b)—

(A) by striking ''controlled substances'' and inserting ''drugs''; and

(B) by inserting ''of subsection (a)'' after ''an order pursuant to paragraph (1) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3)''; and

(4) in subsection (c), by striking ''or an official senior to such Director'' and inserting ''or the Director of the Center for Biologics Evaluation and Re-

search (or an official senior to either such Director)''.

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

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