I

117TH CONGRESS
2D SESSION

H. R. 9476

To protect against seasonal and pandemic influenza, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2022

Mr. LARSEN of Washington (for himself, Ms. ROSS, Mr. BERA, Ms. NORTON, Mr. CARBAJAL, and Ms. BARRAGÁN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Budget, and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To protect against seasonal and pandemic influenza, 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.

This Act may be cited as the ''Protecting America from Seasonal and Pandemic Influenza Act of 2022''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Influenza occurs seasonally each year, and throughout history has caused devastating pandemics. The 1918 influenza pandemic killed an estimated 675,000 Americans.

(2) In an average season, influenza results in 12,000 to 52,000 deaths in the United States, including over 100 pediatric deaths. Additionally, influenza causes hundreds of thousands of hospitalizations and millions of illnesses.

(3) The Council of Economic Advisors issued a report in 2019 estimating that seasonal influenza costs the United States approximately $361,000,000,000 per year, and that an influenza pandemic has the potential to cause up to $3,790,000,000,000 in losses. This report was issued prior to the COVID–19 pandemic, which will cost the United States an estimated $16,000,000,000,000.

(4) Most funding for pandemic influenza preparedness up until fiscal year 2018 was derived from supplemental appropriations that dated back to the 2009 H1N1 pandemic.

(5) Centers for Disease Control and Prevention (in this preamble referred to as the ''CDC'') studies of influenza hospitalization rates by race and eth-

nicity during 10 influenza seasons from 2009 to 2019 showed that people from racial and ethnic minority groups are at higher risk for being hospitalized with influenza.

(6) The COVID–19 pandemic response has been built on the pandemic influenza response ecosystem.

(7) Strategies that increase seasonal influenza vaccination rates will also improve pandemic readiness.

(8) The National Influenza Vaccine Modernization Strategy of 2020–2030 of the Department of Health and Human Services should be implemented as quickly as possible to ensure the Nation's vaccine enterprise is highly responsive, flexible, scalable, and effective at reducing the impact of seasonal and pandemic influenza viruses.

(9) Influenza surveillance has been improved significantly over the last several years by deploying next-generation gene sequencing tools to analyze circulating influenza viruses. The technology allows the CDC to study more influenza viruses faster and in more detail, and to monitor genetic changes in influenza viruses to better understand and improve the effectiveness of influenza vaccines.

(10) Vaccine hesitancy in the United States has reached a tipping point where it is adversely affecting public health. Misinformation is widely available on social media, and traditional sources of information on the value and efficacy of vaccines are not trusted by many Americans, especially those who are vaccine hesitant.

(11) Support for vaccine communication, outreach, and administration across public health and health care settings is critical to drive demand of influenza vaccines, treatments, and medical countermeasures and ensure equitable uptake of these innovations.

SEC. 3. STRENGTHENING AND DIVERSIFYING INFLUENZA VACCINE DEVELOPMENT, MANUFACTURING, AND SUPPLY CHAIN.

(a) TIMELY DELIVERY OF FIRST DOSES OF FINISHED INFLUENZA VACCINE.—

(1) NATIONAL GOAL.—It is a national goal for the United States, not later than 3 years after the date of enactment of this Act, to have the capacity to deliver first doses of finished influenza vaccine within 12 weeks of emergence of an influenza strain with pandemic potential.

(2) PLAN.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Assistant Secretary for Preparedness and Response, and the Director of the Biomedical Advanced Research and Development Authority shall publish a plan to achieve the goal specified in paragraph (1).

(b) UNIVERSAL INFLUENZA VACCINE.—

(1) NATIONAL GOAL.—It is a national goal for the United States, not later than 10 years after the date of enactment of this Act, to have developed a universal influenza vaccine.

(2) PLAN.—

(A) PUBLICATION.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Director of the Biomedical Advanced Research and Development Authority shall publish a plan to achieve the goal specified in paragraph (1) in partnership with vaccine manufacturers.

(B) INTERIM SUPPORT.—The plan under subparagraph (A) shall include provisions, as necessary to achieve such goal, for support over

the period of 5 years following the publication of such plan of the following:

(i) Incremental vaccine efficacy improvements.

(ii) The research workforce.

(c) STRENGTHENING THE VACCINE SUPPLY CHAIN.—

(1) PUBLIC-PRIVATE PARTNERSHIPS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall establish public-private partnerships to strengthen the domestic vaccine supply chain.

(B) DOMESTIC VACCINE SUPPLY CHAIN.—For purposes of this paragraph, the term ''domestic vaccine supply chain'' includes the full domestic supply chain, including—

(i) production of ingredients and manufacturing and distribution of finished vaccines;

(ii) fill-finish capacity; and

(iii) the supply chain of ancillary supplies such as needles and syringes.

(2) EVALUATION OF USING DPA.—The Secretary of Health and Human Services, in coordination with the Administrator of the Federal Emer-

gency Management Agency and the Secretary of Defense, shall—

(A) evaluate the use of the Defense Production Act of 1950 (50 U.S.C. 4501 et seq.) for COVID–19 pandemic response;

(B) not later than 1 year after the date of enactment of this Act, complete such evaluation and submit a report to the Congress on the results of such evaluation; and

(C) include in such report—

(i) recommendations on using the Defense Production Act of 1950 (50 U.S.C. 4501 et seq.) for building domestic capacity to respond to an influenza pandemic; and

(ii) input from external stakeholders.

(d) NATIONAL INFLUENZA VACCINE MODERNIZATION STRATEGY.—The Secretary of Health and Human Services shall—

(1) implement the portions of the National Influenza Vaccine Modernization Strategy 2020–2030 that are within the authority of the Department of Health and Human Services to carry out (under other applicable provisions of law); and

(2) by June 15 each calendar year through 2030, submit to the Congress a report on such implementation.

(e) ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.—Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)—

(A) in paragraph (3), by inserting ", including the pandemic influenza medical countermeasures program under paragraphs (2)(E) and (4)(G) of section 319L(c)" after "qualified pandemic or epidemic products (as defined in section 319F–3)"; and

(B) in paragraph (7), by inserting ", including through the pandemic influenza medical countermeasures program under paragraphs (2)(E) and (4)(G) of section 319L(c)" after "for each such threat"; and

(2) in subsection (d)(2)—

(A) in subparagraph (J), by striking "and" at the end;

(B) by redesignating subparagraph (K) as subparagraph (L); and

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

''(K) evaluate progress with respect to implementing the National Influenza Vaccine Modernization Strategy, issued in June 2020, or any successor strategy; and''.

(f) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) PREPAREDNESS ACTIVITIES.—Section 319L(c) of the Public Health Service Act (42 U.S.C. 247d–7e(c)) is amended—

(A) in paragraph (2)—

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

(ii) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end of the following:

''(E) supporting pandemic influenza countermeasure preparedness.''; and

(B) in paragraph (4), by adding at the end of the following:

''(G) PANDEMIC INFLUENZA MEDICAL COUNTERMEASURES PROGRAM.—In carrying out paragraph (2)(E), the Secretary shall establish and implement a program that—

"(i) supports research and development activities for qualified pandemic or epidemic products (as defined in section 319F–3), including by—

"(I) developing innovative technologies to enhance rapid response to pandemic influenza threats;

"(II) developing influenza vaccines with potential universal vaccination capability;

"(III) developing enhanced influenza vaccines with longer lasting broad spectrum protective immunity against a wider range of antigenically divergent influenza strains;

"(IV) developing novel small- and large-molecule novel influenza antivirals, monoclonal antibodies, and other products that provide better influenza treatment and prevention; and

"(V) implementing the National Influenza Vaccine Modernization Strategy, issued in June 2020, or any successor strategy;

"(ii) ensures readiness to respond to qualified pandemic and epidemic threats, including by—

"(I) supporting development and manufacturing of influenza virus seeds, clinical trial lots, and stockpiles of novel influenza strains;

"(II) supporting the stockpile of influenza antivirals through diversifying and replenishing the existing stockpile of influenza antivirals;

"(III) supporting manufacturing and fill-finish rapid response infrastructure needed to meet the goals of the National Influenza Vaccine Modernization Strategy, issued in June 2020, or any successor strategy; and

"(IV) testing and evaluating pandemic threat rapid response capabilities through regular preparedness drills with key public and private sector partners that examine the range of activities (including production and clinical testing of influenza vaccines)

required to effectively respond to novel threats; and

''(iii) builds, sustains, and replenishes qualified pandemic and epidemic stockpiles of bulk antigen and adjuvant material, including by—

''(I) annually testing the potency and shelf life potential of all existing pandemic and epidemic stockpiles held by the Department of Health and Human Services; and

''(II) developing, and disseminating to key public and private sector partners, a life cycle management plan.''.

(g) AUTHORIZATION OF APPROPRIATIONS.—Section 319L(d) of the Public Health Service Act (42 U.S.C. 247d–7e(d)) is amended by adding at the end the following:

''(3) PANDEMIC INFLUENZA.—To carry out this section and section 2811 with respect to pandemic influenza, in addition to amounts authorized to be appropriated by paragraph (2) and any amounts authorized to be appropriated by section 2811, there is authorized to be appropriated $382,000,000 for each

of the fiscal years 2023 through 2027, to remain available until expended.''.

SEC. 4. PROMOTING INNOVATIVE APPROACHES AND USE OF NEW TECHNOLOGIES TO DETECT, PREVENT, AND RESPOND TO INFLUENZA.

(a) EXPANDED GENOMIC SEQUENCING.—

(1) GRANTS.—The Director of the Centers for Disease Control and Prevention may award grants to State and local laboratories, academic research institutions, and other private entities to expand genomic sequencing.

(2) SOURCES OF DATA.—The sequencing supported pursuant to paragraph (1) may rely on multiple sources of data, including human, animal, plant, and environmental data necessary to track zoonotic diseases.

(b) CENTERS OF EXCELLENCE IN GENOMIC EPIDEMIOLOGY.—The Director of the Centers for Disease Control and Prevention may—

(1) designate Centers of Excellence in Genomic Epidemiology; and

(2) award grants to such Centers of Excellence to establish and implement partnerships between State and local health departments and academic in-

stitutions to improve genomic epidemiology, including through the conduct or support of research.

(c) SENSE OF CONGRESS.—It is the sense of Congress that the Centers for Disease Control and Prevention should support interoperable immunization information systems that enable bidirectional data exchange among States, localities, and community immunization providers.

(d) PRIORITIZING INFLUENZA AND PATHOGEN AGNOSTIC TOOLS.—

(1) NIH.—The Director of the National Institutes of Health may conduct or support basic research prioritizing the development of—

(A) agnostic tools to detect influenza and other pathogens; and

(B) technologies that automate sample preparation for such tools.

(2) BARDA.—The Director of the Biomedical Advanced Research and Development Authority may conduct or support advanced development of novel sequencing modalities prioritizing tools described in paragraph (1)(A) and technologies described in paragraph (1)(B).

(e) DEVELOPMENT OF POINT-OF-PERSON DIAGNOSTICS.—The Director of the Biomedical Advanced Research and Development Authority, in collaboration

with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs, may conduct or support development of rapid, accurate, easily accessible, self-administrable, and readable point-of-person diagnostic tests.

(f) INCORPORATING DIAGNOSTICS SUPPLY CHAIN RESILIENCY INTO INFLUENZA PANDEMIC PLANNING.—The Assistant Secretary for Preparedness and Response, in collaboration with the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, shall—

(1) incorporate diagnostics supply chain resiliency into influenza pandemic planning; and

(2) not later than 1 year after the date of enactment of this Act, publish a plan for rapidly expanding public and private diagnostic testing capacity (including at clinical laboratories, at public health department laboratories, and by means of self-testing) in an influenza pandemic.

(g) COORDINATING THE INTEGRATION OF POINT-OF-PERSON DIAGNOSTIC TEST RESULTS IN DATABASES.—The Director of the Centers for Disease Control and Prevention shall carry out activities to provide for the coordination of the integration of data and results from point-

of-person diagnostic tests in local, State, and Federal health databases.

(h) SCALING UP PROPHYLACTIC INFLUENZA ANTIBODY PRODUCTS THAT ADDRESS GAPS IN COVERAGE.—The Director of the Biomedical Advanced Research and Development Authority may conduct or support novel preventive approaches, including those still in preclinical and clinical stages, to rapidly scale up prophylactic influenza antibody products that address gaps in vaccine coverage.

(i) MODERNIZING POTENCY ASSAYS.—The Commissioner of Food and Drugs shall work with vaccine manufacturers to modernize potency assays across a variety of manufacturing technologies so as to reduce by 6 weeks the period required to first evaluate new vaccine candidates during a pandemic.

(j) IMPROVED INFLUENZA THERAPEUTICS.—The Director of the Biomedical Advanced Research and Development Authority may conduct or support improved influenza therapeutics that—

(1) are more broadly protective; and

(2) meet the needs of high-risk and high-exposure patients.

(k) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a plan to

strengthen and diversify the public health and health care workforce so as to ensure the capacity of such workforce to effectuate advances pursuant to subsections (a) through (j).

SEC. 5. INCREASING INFLUENZA VACCINE AND THERAPEUTICS ACCESS AND COVERAGE ACROSS ALL POPULATIONS.

(a) ANNUAL REPORT ON PUBLIC COMMUNICATION STRATEGY.—The Director of the Centers for Disease Control and Prevention shall submit an annual report to the Congress on the public communication strategy of the Centers to increase public confidence in the safety and effectiveness of vaccines.

(b) SENSE OF CONGRESS.—It is the sense of Congress that the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Secretary of Defense, the Secretary of Veterans Affairs, the Administrator of the Centers for Medicare & Medicaid Services, and the Commissioner of Food and Drugs should support research using large data sets from multiple sources of health data to further support and evaluate vaccine safety and effectiveness over multiple influenza seasons.

(c) ADDRESSING MISINFORMATION AND DISINFORMATION.—The Secretary of Health and Human

Services shall create partnerships to address misinformation and disinformation with respect to influenza vaccines.

(d) COMMUNICATIONS PUBLIC-PRIVATE PARTNERSHIP.—The Secretary of Health and Human Services may provide for the establishment of a communications public-private partnership initiative for increasing vaccine confidence that—

(1) includes an independent, nongovernmental, nonprofit entity;

(2) supports behavioral research evaluating individual behavior analysis and influence;

(3) identifies and targets vaccine hesitant individuals; and

(4) provides information on vaccine safety and effectiveness.

(e) INCORPORATING HEALTH EQUITY INTO SEASONAL AND PANDEMIC INFLUENZA PLANNING AND RESPONSE.—The Director of the Centers for Disease Control and Prevention and the Assistant Secretary for Preparedness and Response shall—

(1) incorporate health equity into the seasonal and pandemic influenza planning and response programs overseen by such officials; and

(2) in so doing—

(A) emphasize the inclusion of all populations; and

(B) include strategies to reach communities of color, communities with lower socioeconomic status, seniors, and individuals with disabilities.

(f) REPORT ON LESSONS LEARNED FROM COVID–19 FEDERAL RETAIL PHARMACY PROGRAM.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) submit a report to the Congress on lessons learned from the COVID–19 Federal Retail Pharmacy Program; and

(2) identify positive aspects of such Program that could be applied with respect to influenza.

(g) CREATING ADMINISTRATION PATHWAYS.—The Secretary of Health and Human Services may award grants to States to create administration pathways for pharmacy personnel to administer influenza vaccines, in order to increase vaccination rates for adults and children.

(h) STRATEGIC NATIONAL STOCKPILE.—The Secretary of Health and Human Services shall incorporate into the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)

products needed to respond to pandemic influenza, including through—

(1) dynamic management of aging antivirals; and

(2) diversification of stockpiled products.

(i) MONITORING AND DISTRIBUTING INFLUENZA ANTIVIRAL SUPPLIES.—The Secretary of Health and Human Services shall—

(1) monitor influenza antiviral supplies throughout the country; and

(2) establish a process, to be used in pandemic situations, to distribute products rapidly and effectively to areas of urgent need in close coordination with manufacturers and State and local health officials.

(j) PLAN FOR ENSURING ACCESS TO APPROPRIATE INFLUENZA THERAPEUTICS AND PROPHYLAXIS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall publish a plan for ensuring access to appropriate influenza therapeutics and prophylaxis for—

(A) high-risk patients, such as nursing home and pediatric patients; and

(B) high-exposure patients, such as first responders and health care workers.

(2) COMMUNICATIONS EFFORTS.—The plan required by paragraph (1) shall include communications efforts to educate the public about the benefits of early use of influenza therapeutics and prophylaxis.

SEC. 6. AUTHORIZING SUSTAINABLE FUNDING FOR THE INFLUENZA ECOSYSTEM.

(a) INFLUENZA PLANNING AND RESPONSE PROGRAM.—There is authorized to be appropriated $251,000,000 for fiscal year 2025 and each subsequent fiscal year for programs and activities of the Centers for Disease Control and Prevention relating to influenza planning and response.

(b) STRATEGIC NATIONAL STOCKPILE.—There is authorized to be appropriated $1,657,000,000 for fiscal year 2023 and each subsequent fiscal year for the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(c) HOSPITAL PREPAREDNESS PROGRAM.—There is authorized to be appropriated $474,000,000 for fiscal year 2023 and each subsequent fiscal year for Hospital Preparedness Program of the Assistant Secretary for Preparedness and Response.

(d) UNIVERSAL FLU VACCINE RESEARCH.—There is authorized to be appropriated $260,000,000 for fiscal year 2023 and each subsequent fiscal year for research of the National Institutes of Health to develop a universal flu vaccine.

(e) IMMUNIZATION PROGRAM.—There is authorized to be appropriated $1,130,000,000 for fiscal year 2023 and each subsequent fiscal year for the immunization program of the Centers for Disease Control and Prevention under section 317 of the Public Health Service Act (42 U.S.C. 247b).

(f) PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAM.—There is authorized to be appropriated $824,000,000 for fiscal year 2023 and each subsequent fiscal year for the Public Health Emergency Preparedness Program of the Centers for Disease Control and Prevention.

(g) INFECTIOUS DISEASE RAPID RESPONSE RESERVE FUND.—There is authorized to be appropriated $35,000,000 for fiscal year 2023 and each subsequent fiscal year for the Infectious Disease Rapid Response Reserve Fund of the Centers for Disease Control and Prevention.

(h) DATA MODERNIZATION INITIATIVE.—There is authorized to be appropriated $250,000,000 for fiscal year

2023 and each subsequent fiscal year for the Public Health Data Modernization Initiative of the Centers for Disease Control and Prevention.

(i) HEALTH DEFENSE OPERATIONS BUDGET MATTERS.—

(1) DESIGNATION.—Section 251(b)(2) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 901(b)(2)) is amended by adding at the end the following:

"(F) HEALTH DEFENSE OPERATIONS.—(i) If, for any fiscal year, appropriations for discretionary accounts are enacted that the Congress designates in statute on an account by account basis as being for health defense operations, then the adjustment for that fiscal year shall be the total of such appropriations for that fiscal year.

"(ii) Any report or explanatory statement accompanying an appropriations Act that contains an account with amounts that are designated as being for health defense operations pursuant to clause (i) shall specify each program, project, or activity that will be funded by such amounts, and a specific dollar amount pro-

vided for each such program, project, or activity.''.

(2) PROFESSIONAL BYPASS BUDGET.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by inserting after section 402B the following:

''SEC. 402C. HEALTH DEFENSE OPERATIONS PROFESSIONAL BYPASS BUDGET.

''(a) IN GENERAL.—For fiscal year 2024 and each fiscal year thereafter, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Assistant Secretary for Preparedness and Response shall prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for amounts to be designated as being for health defense operations pursuant to subparagraph (F) of section 251(b)(2) of the Balanced Budget and Emergency Deficit Control Act of 1985.

''(b) PROGRAMS, PROJECTS, AND ACTIVITIES.—Any budget estimate submitted pursuant to subsection (a) by the Director shall include any program, project, or activity

that received funds designated under such subparagraph (F) for the fiscal year during which such budget is submitted, except that the Director may modify the programs, projects, or activities contained in such budget estimate as circumstances warrant.''.

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