I

118TH CONGRESS
1ST SESSION

H. R. 5846

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2023

Mr. LARSEN of Washington (for himself, Ms. BARRAGÁN, Mr. BERA, Ms. NORTON, Ms. ROSS, Mr. CARBAJAL, and Mr. TORRES of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Financial Services, and the Budget, 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 2023''.

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) Influenza diagnosis and surveillance has improved significantly over the last several years by advances in influenza testing. Timely infection control and prevention strategies would be significantly bolstered by accurate and readily accessible at-home diagnostic tests. Rapid diagnostics can improve access for underserved populations and allow for better antibiotic stewardship.

(11) 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.

(12) 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, THERAPEUTICS, AND DIAGNOSTICS 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—

(i) establish public-private partnerships to strengthen the domestic vaccine supply chain; and

(ii) evaluate the capabilities, capacity, and utilization of such partnerships, including by assessing and testing relevant logistical and interoperable technology with stakeholders in the 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 Emergency 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)(H) 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)(H) 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:

''(H) 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 alternative vaccine delivery approaches;

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

''(VI) developing innovative technologies to enhance rapid diagnosis of influenza; and

''(VII) 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;

"(IV) supporting the stockpile of influenza testing equipment and supplies; and

"(V) 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 diagnostics, vaccines, and thera-

peutics) 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 shelflife 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 $335,000,000 for each

of the fiscal years 2024 through 2028, to remain available until expended.''.

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

(a) 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.

(b) PRIORITIZING INFLUENZA, INFLUENZA COMBINATION, 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).

(c) DEVELOPMENT OF POINT-OF-CARE AND SELF-TESTING 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 diagnostic tests that are readable at the point of care or at home.

(d) 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, the Director of the Centers for Disease Control and Prevention, the Secretary of Commerce, and the Secretary of Transportation, shall—

(1) incorporate diagnostics supply chain resiliency into influenza pandemic planning that supports a health care system that tests to treat and bolsters testing and vaccine delivery supply chains; 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, including addressing transportation infrastructure, the need for sterilization, and sourcing critical raw materials, components, and parts.

(e) 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 preventive approaches, including those still in preclinical and clinical stages, to rapidly scale up preexposure prophylactic influenza antibody products that address influenza infection.

(f) 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.

(g) 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.

SEC. 5. INCREASING INFLUENZA VACCINE, THERAPEUTICS, AND TESTING 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.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall create partnerships to address misinformation and disinformation with respect to influenza vaccines.

(2) REQUIREMENTS.—The partnerships under paragraph (1) shall—

(A) build on lessons learned from COVID–19; and

(B) allow for dissemination of best practices and lessons learned between partnering organizations.

(3) MEMBERS.—The members of the partnerships under paragraph (1) shall include representatives of organizations with experience working with vulnerable populations, including—

(A) individuals with chronic health conditions;

(B) older Americans;

(C) parents of young children;

(D) pregnant people;

(E) Tribal communities; and

(F) racial and ethnic minorities.

(4) CONFERRING WITH PARTNERING ORGANIZATIONS.—The Secretary of Health and Human Services shall confer with organizations represented in partnerships under paragraph (1)—

(A) in advance of each seasonal influenza season, on messaging and communications; and

(B) at the end of each seasonal influenza season, on best practices and lessons learned.

(5) REPORT TO CONGRESS.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on the partnerships created, and activities conducted, under this section.

(d) COMMUNICATIONS PUBLIC-PRIVATE PARTNERSHIP.—

(1) IN GENERAL.—Not later than six months after the date of enactment of this Act, the Secretary of Health and Human Services shall implement a targeted demonstration project that provides for the establishment of a communications public-private partnership initiative for increasing vaccine confidence.

(2) REQUIREMENTS.—The demonstration project under paragraph (1) shall—

(A) be implemented through an independent, nongovernmental, nonprofit entity;

(B) focus on individuals with chronic illness or other comorbidities who tend to have worse clinical outcomes from influenza (such as individuals with heart disease or diabetes, and racial and ethnic minorities);

(C) support behavioral research around sources of vaccine hesitancy; and

(D) develop and implement a targeted, multimodal communications campaign, using internet platforms, television, and nontraditional targeted social media and community outreach in an effort to reach individuals who may be especially vaccine hesitant.

(3) REPORT.—Not later than six months after completion of the demonstration project under paragraph (1), the Secretary of Health and Human Services shall—

(A) prepare a report on the demonstration project, including an evaluation of the project's methods, findings, and results; and

(B) make such report publicly available on the website of the Department of Health and Human Services.

(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, including addressing barriers to vaccinations, therapeutics, and diagnostics in the point-of-care and at-home self-testing settings.

(f) EXPANDING ACCESS TO INFLUENZA TREATMENT AND ADOPTING LESSONS LEARNED FROM COVID–19 FEDERAL RETAIL PHARMACY PROGRAM.—

(1) REPORT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on lessons learned from the COVID–19 Federal Retail Pharmacy Program, including aspects of the program that could be applied with respect to multianalyte tests that target COVID–19 as well as influenza and other upper respiratory viruses.

(2) DEMONSTRATION PROJECT.—

(A) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall initiate an influenza test-to-treat demonstration project that builds on the test-to-treat model employed for COVID–19.

(B) LENGTH; LOCATIONS.—This demonstration project under subparagraph (A) shall run for the length of one seasonal influenza season and be based in one or more of the following locations:

(i) Facilities that serve vulnerable populations, such as populations who are in long-term care facilities, are 65 years of age or older, may have other medical conditions, and will be in unavoidable close contact with others.

(ii) Federal health care facilities that serve at-risk and vulnerable communities, such as Indian Health Service clinics, Federally qualified health centers (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and facilities of the Department of Veterans Affairs.

(iii) Existing COVID–19 test-to-treat sites at retail pharmacies, potentially in specific geographic areas with historically high mortality from influenza.

(iv) Other appropriate locations identified by the Secretary of Health and Human Services, in consultation with external stakeholder organizations, to test the operational feasibility and impact of influenza test-to-treat programs.

(3) REPORT.—Not later than six months after completion of the demonstration project, the Secretary of Health and Human Services shall—

(A) prepare a report on the demonstration project under paragraph (1), including an evaluation of the project's methods, findings, and results; and

(B) make such report publicly available on the website of the Department of Health and Human Services.

(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, tests, and therapeutics, in order to increase vaccination,

testing, and relevant treatment as needed 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 antivirals;

(2) vendor-managed inventory of testing equipment and supplies;

(3) replenishment of aging antivirals, testing equipment, supplies, and other products; and

(4) 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 publicly report challenges in availability in any region, State, county, or metropolitan area; and

(2) establish a process, to be used in the case of a pandemic or during times when influenza antiviral supply availability is challenged, to ensure rapid and effective distribution of products to areas

of urgent need in close coordination with manufacturers, distributors, and State and local health officials.

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

(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, preexposure prophylaxis influenza antibody products, and influenza diagnostics, including during times when availability is challenged in certain regions or localities, for—

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

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

(C) low-income individuals, individuals covered by Medicaid, uninsured individuals, Tribal communities, and other underserved populations.

(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 diagnostics, therapeutics, and preexposure prophylaxis products.

(k) GAO REVIEW ON TRANSFERRING COVID–19 TECHNOLOGIES.—

(1) IN GENERAL.—Not later than six months after the date of enactment of this Act, the Comptroller General of the United States shall conduct a review of the technology and systems utilized by the Centers for Disease Control and Prevention, the Administration for Strategic Preparedness and Response, Operation Warp Speed, the Countermeasure Acceleration Group, H–CORE, and other current and historical departments and agencies involved in the COVID–19 response for surveillance and tracking of COVID–19 cases, treatments, and vaccines, with particular focus on—

(A) disease surveillance;

(B) vaccine surveillance; and

(C) vaccine effectiveness.

(2) SCOPE.—The review under paragraph (1) shall include—

(A) assessment of which technology and systems can be applied to, or can be altered to apply to, influenza and other infectious diseases; and

(B) formulation of recommendations for applying and altering technologies and systems as described in subparagraph (A).

(3) REPORT BY HHS TO CONGRESS.—Not later than 30 days after completion of the review required by paragraph (1), the Secretary of Health and Human Services shall submit a report to the Congress on the timeline and actions necessary to implement the recommendations formulated under paragraph (2)(B).

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

(a) INFLUENZA PLANNING AND RESPONSE PROGRAM.—There is authorized to be appropriated $231,000,000 for fiscal year 2024 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 $965,000,000 for fiscal year 2024 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 $305,000,000 for fiscal year

2024 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 $270,000,000 for fiscal year 2024 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 $682,000,000 for fiscal year 2024 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 $735,000,000 for fiscal year 2024 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 2024 and each subsequent fiscal year for the Infectious Disease Rapid Response Re-

serve Fund of the Centers for Disease Control and Prevention.

(h) DATA MODERNIZATION INITIATIVE.—There is authorized to be appropriated $175,000,000 for fiscal year 2024 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:

"(H) 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 provided 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 2025 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 (H) 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 (H) 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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