I

118TH CONGRESS
2D SESSION

H. R. 9942

To support the development, licensing, and initial manufacturing of a human vaccine for valley fever.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2024

Mr. DUARTE (for himself, Mr. STANTON, Mr. SCHWEIKERT, Mr. COSTA, Mr. VALADAO, Ms. TOKUDA, and Mr. OBERNOLTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To support the development, licensing, and initial manufacturing of a human vaccine for valley fever.

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 "Valley Fever Awareness and Vaccine Development and Manufacturing Act of 2024".

SEC. 2. VALLEY FEVER VACCINE NATIONAL STRATEGY.

(a) WHOLE OF GOVERNMENT APPROACH.—

(1) IN GENERAL.—The Secretary shall coordinate with the relevant agency heads to support the

development, licensing, and initial manufacturing of a human vaccine for valley fever.

(2) CONSULTATION.—In implementing paragraph (1), the Secretary shall consult with expert stakeholders on valley fever and vaccine development and manufacturing.

(3) VACCINE COORDINATOR.—

(A) APPOINTMENT.—Not later than 60 days after the date of the enactment of this section, the Secretary shall appoint a Vaccine Coordinator from among the officials at the Food and Drug Administration or the National Institutes of Health.

(B) DUTIES.—The Vaccine Coordinator shall—

(i) act as a single point of contact within the Federal Government on matters related to implementing this section;

(ii) not later 180 days after the date of the enactment of this section, and every 180 days thereafter, publish on the internet website of the Department of Health and Human Services a report that describes all of the activities undertaken pursuant to this section;

(iii) not later than six months after the date of the enactment of this section, and every six months thereafter, convene a meeting with the relevant agency heads and expert stakeholders to advance the development, approval, and manufacturing of a valley fever vaccine; and

(iv) identify ways to—

(I) expedite regulatory review and licensing of a safe and effective valley fever vaccine, consistent with applicable safety and other requirements; and

(II) to advance the development, licensing, and manufacturing of such a vaccine.

(b) VALLEY FEVER VACCINE DEVELOPMENT NATIONAL STRATEGY.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of this section, the Secretary, acting through the Vaccine Coordinator and in consultation with the relevant agency heads and expert stakeholders, shall develop and publish on the internet website of the Department of Health and Human Services a national strategy to develop,

license, and manufacture a valley fever vaccine by no later than January 1, 2034.

(2) CONTENT.—The national strategy shall contain—

(A) a statement of science on valley fever, including current efforts to develop a valley fever vaccine;

(B) an assessment of the status of valley fever vaccine development and manufacturing, including vaccine market viability;

(C) an overview of Federal research funding made available over the 10 years preceding the date of the enactment of this section to support valley fever vaccine development, including pre-clinical and clinical work, licensing, and manufacturing;

(D) identifiable and achievable benchmarks for vaccine development and manufacturing, including a timeline for valley fever vaccine development and manufacturing consistent with the timeline in paragraph (1);

(E) Federal, State, and local funding priorities and opportunities that actively support the development or manufacturing of a valley fever vaccine;

(F) recommendations for coordination between Federal agencies and departments to reduce any overlap with respect to valley fever vaccine development and manufacturing reviews, permits, and licensing;

(G) recommendations on actions Federal agencies and departments may take to expedite the development or manufacturing of a valley fever vaccine that do not require congressional authorization;

(H) recommendations on actions that Congress may take to expedite the development and manufacturing of a valley fever vaccine; and

(I) an assessment of—

(i) the prevalence of valley fever in the United States;

(ii) the cost associated with treating valley fever in the United States; and

(iii) the economic impact of valley fever in the United States.

(3) PUBLIC COMMENT.—

(A) IN GENERAL.—Not later than six months after the date of the enactment of this section, the Secretary shall publish a proposed draft of the national strategy in the Federal

Register and provide an opportunity for public comment on such national strategy.

(B) CONSIDERATION OF COMMENTS.—In finalizing the national strategy, the Secretary shall consider public comments received pursuant to subparagraph (A).

(4) EXPERT CONSULTATION.—In developing the national strategy, the Secretary, acting through the Vaccine Coordinator, shall—

(A) consult with the relevant agency heads and expert stakeholders; and

(B) hold not less than two in-person meetings with the relevant agency heads and expert stakeholders, of which one shall be conducted prior to receiving public comments on the national strategy and one shall be conducted after such public comments are received.

SEC. 3. GUIDANCE ON DEVELOPMENT, MANUFACTURING, AND APPROVAL OF VALLEY FEVER VACCINE.

The Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention shall issue guidance on the development and manufacturing of a valley fever vaccine and approval for use of such vaccine, as applicable.

SEC. 4. VACCINE DEVELOPMENT AND MANUFACTURING.

(a) VACCINE DEVELOPMENT PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Vaccine Coordinator and in consultation with the relevant agency heads, shall carry out a program of—

(A) entering into contracts with eligible entities to support and advance the development of a valley fever vaccine; or

(B) awarding grants to eligible entities under paragraph (2).

(2) GRANT PROGRAM.—

(A) IN GENERAL.—The Secretary may award grants pursuant to paragraph (1)(B) to support and advance the development of a valley fever vaccine.

(B) PRIORITY.—In awarding grants under subparagraph (A), the Secretary shall give priority to applicants that have commenced Phase 1, 2, or 3 clinical trials on a valley fever vaccine.

(C) AWARD AMOUNT.—The amount of a grant under this paragraph shall be not less than $500,000 and not more than $2,500,000.

(3) COMMENCEMENT.—Not later than 180 days after the date of the enactment of this section, the

Secretary shall commence the program under paragraph (1).

(4) CONSULTATION REQUIREMENT.—In carrying out this subsection, the Secretary shall consult with physicians, medical providers, scientists, researchers, nonprofit entities, advocacy groups, and other individuals with expertise in valley fever research and vaccine development.

(b) VACCINE MANUFACTURING PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Vaccine Coordinator and in consultation with the relevant agency heads, shall—

(A) enter into contracts with eligible entities to support and advance the manufacturing of a valley fever vaccine; or

(B) award grants to eligible entities under paragraph (2).

(2) GRANT PROGRAM.—

(A) IN GENERAL.—The Secretary may award grants pursuant to paragraph (1)(B) to support and advance the manufacturing of a valley fever vaccine.

(B) AWARD AMOUNT.—The amount of a grant under this paragraph shall be not less than $500,000 and not more than $5,000,000.

(3) COMMENCEMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary shall commence the programs under paragraph (1).

(4) CONSULTATION REQUIREMENT.—In carrying out this subsection, the Secretary shall consult with vaccine manufacturing experts and other individuals with expertise in valley fever research and vaccine manufacturing.

SEC. 5. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Secretary—

(1) $1,000,000 for fiscal year 2026 to carry out section 2(b);

(2) $25,000,000 for the period of fiscal years 2025 through 2030 to carry out section 4(a); and

(3) $25,000,000 for the period of fiscal years 2025 through 2030 to carry out section 4(b).

SEC. 6. NATIONAL VALLEY FEVER REGISTRY.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–8. NATIONAL VALLEY FEVER REGISTRY.

"(a) DATA COLLECTION AND REGISTRY.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, if scientifically advisable, may—

"(A) carry out a system to collect non-personally identifiable voluntary data on coccidioidomycosis (referred to in this section as 'valley fever') and other fungal diseases that can be confused with valley fever or misdiagnosed as valley fever, including information with respect to the incidence and prevalence of such diseases in the United States; and

"(B) maintain a national registry (referred to in this section as the 'National Valley Fever Registry') for the collection and storage of the data collected pursuant to subparagraph (A) to develop a population-based registry of cases in the United States of valley fever and other fungal diseases that can be confused with valley fever or misdiagnosed as valley fever.

"(2) REQUIRED COMMENCEMENT TIMING.—The authority to commence activities under paragraph (1) shall terminate on the date that is one year after the receipt of the report described in subsection (b)(4).

''(b) ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish the Advisory Committee on the National Valley Fever Registry (referred to in this section as the 'Advisory Committee').

''(2) MEMBERSHIP.—The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Director of Centers for Disease Control and Prevention, of which—

''(A) two-thirds of the members of the Advisory Committee shall represent Federal agencies, including at least—

''(i) two members representing the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, one such member representing the National Institute of Allergy and Infectious Diseases;

''(ii) one member representing the Department of Defense;

"(iii) one member representing the Centers for Disease Control and Prevention;

"(iv) one member who is a clinician with expertise on valley fever and related diseases;

"(v) one member who is an epidemiologist with experience in data registries;

"(vi) one member who is a statistician;

"(vii) one member who is an ethicist; and

"(viii) one member who is an expert in privacy regulations under the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–6); and

"(B) one-third of the members of the Advisory Committee shall be members of the public, including at least—

"(i) one member representing national and voluntary health associations;

"(ii) one member representing patients with valley fever or their family members;

"(iii) one member representing clinicians with expertise on valley fever and related diseases;

"(iv) one member representing epidemiologists with expertise in data registries; and

"(v) one member representing individuals with an interest in developing and maintaining the National Valley Fever Registry.

"(3) DUTIES.—The Advisory Committee shall—

"(A) review information and make recommendations to the Secretary concerning—

"(i) the development and maintenance of the National Valley Fever Registry;

"(ii) the type of information to be collected and stored in the National Valley Fever Registry;

"(iii) the manner in which such data is to be collected;

"(iv) the use and availability of such data including guidelines for such use; and

"(v) the collection of information about diseases and disorders that primarily

affect motor neurons that are considered essential to furthering the study and cure of valley fever; and

''(B) oversee the National Valley Fever Registry, if the Secretary establishes the National Valley Fever Registry.

''(4) REPORT.—Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee shall submit a report to the Secretary containing the information reviewed and each recommendation made under paragraph (3)(A).

''(5) TERMINATION.—The Advisory Committee shall terminate on the date that is seven years after the date on which the report required under paragraph (4) is submitted.

''(c) GRANTS.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on valley fever and other fungal diseases that can be confused with valley fever or misdiagnosed as valley fever.

"(2) COMMENCEMENT.—After receiving the report under subsection (b)(4), the Secretary may commence making awards under paragraph (1).

"(d) COORDINATION WITH FEDERAL, STATE, AND LOCAL REGISTRIES.—

"(1) IN GENERAL.—In establishing the National Valley Fever Registry, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

"(A) identify, build upon, expand, and coordinate among existing data, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

"(i) any registry previously supported by the Centers for Disease Control and Prevention;

"(ii) State-based valley fever registries;

"(iii) the National Vital Statistics System of the National Center for Health Statistics; and

"(iv) any other existing or relevant databases that collect or maintain informa-

tion on each fungal disease recommended by the Advisory Committee; and

''(B) provide for research access to valley fever data, as recommended by the Advisory Committee, to the extent permitted by applicable statutes and regulations and in a manner that protects privacy consistent with applicable privacy statutes and regulations.

''(2) COORDINATION WITH THE NATIONAL INSTITUTES OF HEALTH.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the Director of the National Institutes of Health.

''(e) NATIONAL AND VOLUNTARY HEALTH ASSOCIATIONS DEFINED.—In this section, the term 'national and voluntary health associations' means a national nonprofit organization with chapters or other affiliated organizations in States throughout the United States that have—

''(1) experience serving the population of individuals with valley fever; and

''(2) have demonstrated experience in valley fever research, care, and patient services.''.

SEC. 7. DEFINITIONS.

In this Act—

(1) the term ''eligible entity'' means—

(A) an academic institution;

(B) a nonprofit organization;

(C) a State or local government; and

(D) a private entity;

(2) the term ''expert stakeholders'' means academic institutions, advocacy groups, clinicians, patient groups, researchers, public health officials, scientists, and vaccine manufactures with expertise in valley fever, vaccine development, or vaccine manufacturing;

(3) the term ''relevant agency heads'' means—

(A) the Director of the National Institutes of Health;

(B) the Director of the Biomedical Advanced Research and Development Authority;

(C) the Commissioner of Food and Drugs; and

(D) such other heads of Federal agencies and departments as the Secretary determines relevant;

(4) the term ''Secretary'' means the Secretary of Health and Human Services;

(5) the term ''valley fever'' means coccidioidomycosis; and

(6) the term ''Vaccine Coordinator'' means the valley fever vaccine development coordinator appointed under section 2(a)(3).

○