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116TH CONGRESS
1ST SESSION

H. R. 2858

To support endemic fungal disease research, incentivize fungal vaccine development, discover new antifungal therapies and diagnostics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2019

Mr. MCCARTHY (for himself, Mr. SCHWEIKERT, Ms. BASS, and Mr. STANTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To support endemic fungal disease research, incentivize fungal vaccine development, discover new antifungal therapies and diagnostics, 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) IN GENERAL.—This Act may be cited as the ''Finding Orphan-disease Remedies With Antifungal Research and Development Act of 2019'' or the ''FORWARD Act of 2019''.

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

SEC. 2. CONTINUING SUPPORT FOR RESEARCH ON ENDEMIC FUNGAL DISEASES.

The Public Health Service Act is amended by inserting after section 320A of such Act (42 U.S.C. 247d–8) the following new section:

"SEC. 320B. ENDEMIC FUNGAL DISEASES.

''(a) IN GENERAL.—The Secretary shall continue to conduct or support epidemiological, basic, translational, and clinical research related to endemic fungal diseases, including coccidioidomycosis (commonly known as and referred to in this section as 'Valley Fever').

''(b) REPORTS.—The Secretary shall ensure that each triennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to endemic fungal diseases, including Valley Fever.

''(c) ENDEMIC FUNGAL DISEASE WORKING GROUP.—

''(1) ESTABLISHMENT.—The Secretary shall establish a working group, to be known as the En-

demic Fungal Disease Working Group (referred to in this section as the 'Working Group'), comprised of representatives of appropriate Federal agencies and other non-Federal entities—

"(A) to provide expertise and to review all efforts within the Department of Health and Human Services related to endemic fungal disease;

"(B) to help ensure interagency coordination and minimize overlap with respect to such disease; and

"(C) to examine research priorities with respect to such disease.

"(2) RESPONSIBILITIES.—The Working Group shall—

"(A) not later than 2 years after the date of enactment of the FORWARD Act of 2019, develop or update a summary of—

"(i) ongoing endemic fungal disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with an endemic fungal disease;

"(ii) advances made pursuant to such research;

"(iii) Federal activities related to endemic fungal disease, including—

"(I) epidemiological activities related to endemic fungal disease; and

"(II) basic, clinical, and translational endemic fungal disease research related to the pathogenesis, prevention, diagnosis, and treatment of endemic fungal disease;

"(iv) gaps in endemic fungal disease research described in clause (iii)(II);

"(v) the Working Group's meetings required under paragraph (4); and

"(vi) the comments received by the Working Group;

"(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

"(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding sci-

entific advances, research questions, and surveillance activities.

''(3) MEMBERSHIP.—The members of the Working Group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

''(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of the following:

''(i) The Office of the Assistant Secretary for Health.

''(ii) The Food and Drug Administration.

''(iii) The Centers for Disease Control and Prevention.

''(iv) The National Institutes of Health.

''(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

''(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

''(i) Physicians and other medical providers with experience in diagnosing and treating endemic fungal disease.

''(ii) Scientists or researchers with expertise.

''(iii) Patients and their family members.

''(iv) Nonprofit organizations that advocate for patients with respect to endemic fungal disease.

''(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

''(4) MEETINGS.—The Working Group shall meet annually.

''(5) REPORTING.—Not later than 2 years after the date of enactment of the FORWARD Act of 2019, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

''(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the

House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

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

''(6) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

''(7) SUNSET.—The Working Group under this section shall terminate 5 years after the date of enactment of the FORWARD Act of 2019.

''(d) ENDEMIC FUNGAL DISEASE DEFINED.—In this section, the term 'endemic fungal disease' means blastomycosis, coccidioidomycosis, histoplasmosis, and sporotrichosis.''.

SEC. 3. ENDEMIC FUNGAL DISEASE FEDERAL-STATE MATCH PILOT PROGRAM.

(a) IN GENERAL.—

(1) GRANTS.—For each of fiscal years 2021 through 2025, the Secretary of Health and Human Services shall, subject to the availability of appropriations, award grants through a competitive process to eligible entities to conduct research with re-

spect to endemic fungal diseases, including coccidioidomycosis.

(2) PEER REVIEW.—Any research supported under this section shall be subject to peer review in accordance with the requirements applicable to research supported by the National Institutes of Health under section 492 of the Public Health Service Act (42 U.S.C. 289a).

(b) ELIGIBILITY.—An entity eligible to receive a grant under this section is a State or local public hospital, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), a public health department, or a nonprofit organization that has been provided funds from State or local government sources for epidemiological, basic, translational, and clinical research on endemic fungal diseases.

(c) APPLICATION.—An entity seeking a grant under this section shall submit an application to the Secretary—

(1) in such form and manner as the Secretary shall prescribe;

(2) that contains a certification that the entity has received the funds described in subsection (b) and that specifies the amount of such funds; and

(3) that contains such other information as the Secretary may require.

(d) AMOUNT OF GRANT.—The amount of a grant under this section shall equal (to the extent practicable) the amount of funds received from State or local government sources for the research that is the subject of the grant.

(e) ENDEMIC FUNGAL DISEASE DEFINED.—In this section, the term ''endemic fungal disease'' means blastomycosis, coccidioidomycosis, histoplasmosis, and sporotrichosis.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $8,000,000 for each of fiscal years 2021 through 2025, to remain available until expended.

(g) SUNSET.—The Secretary may not award grants under this section on or after October 1, 2025.

SEC. 4. FDA GUIDANCE FOR INDUSTRY ON DEVELOPMENT OF DIAGNOSTICS AND ANTIFUNGAL DRUGS AND VACCINES FOR VALLEY FEVER.

(a) DRAFT GUIDANCE.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance for industry for the purposes of assisting entities seeking approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or licensure under section 351

of the Public Health Service Act (42 U.S.C. 262) of antifungal therapies, diagnostics, or vaccines, specifically therapies, diagnostics, and vaccines designed to diagnose, treat, or prevent coccidioidomycosis (commonly known as Valley Fever).

(b) FINAL GUIDANCE.—Not later than 18 months after the close of the public comment period on the draft guidance issued pursuant to subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance.

(c) WORKSHOPS; GOOD GUIDANCE PRACTICES.—In developing and issuing the guidance required by this section, the Secretary of Health and Human Services shall hold at least 2 public workshops.

SEC. 5. PRIORITY REVIEW; FAST TRACK PRODUCT.

(a) PRIORITY REVIEW.—

(1) IN GENERAL.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by striking ''then the Secretary shall give priority review to the first application submitted for approval for such drug under section 505(b)'' and inserting ''or if the drug is a biological product intended to treat blastomycosis, coccidioidomycosis, histoplasmosis, or sporotrichosis,

then the Secretary shall give priority review to the first application submitted for approval for such drug under section 505(b) of this Act or section 351(a) of the Public Health Service Act''.

(2) APPLICABILITY.—The amendment made by paragraph (1) applies to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) only if such application is submitted on or after the date of enactment of this Act.

(b) FAST TRACK PRODUCT.—Section 506(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(b)(1)) is amended by striking ''or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' and inserting ''if the Secretary designates the drug as a qualified infectious disease product under section 505E(d), or if the drug is a biological product intended to treat blastomycosis, coccidioidomycosis, histoplasmosis, or sporotrichosis''.

SEC. 6. PRIORITY REVIEW VOUCHERS FOR PRODUCTS FOR PREVENTION OR TREATMENT OF ENDEMIC FUNGAL DISEASES.

Section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)) is amended—

(1) by redesignating subparagraph (S) as subparagraph (T); and

(2) by inserting after subparagraph (R) the following:

''(S) Blastomycosis, coccidioidomycosis, histoplasmosis, and sporotrichosis.''.

SEC. 7. ESTABLISHMENT OF ANTIFUNGAL RESISTANCE RESEARCH PROGRAM MODELED ON THE CARB–X PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out a program, modeled on the Combating Antibiotic Resistant Bacteria Accelerator program of the Department of Health and Human Services (commonly referred to as ''CARB–X''), for research with respect to antifungal resistance, including therapies, diagnostics, and vaccines, including for coccidioidomycosis.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out subsection (a) $10,000,000 for each of fiscal years 2021 through 2025, to remain available until expended.

SEC. 8. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL DATA SECURITY FOR ENDEMIC FUNGAL DISEASE RESEARCH.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following new section:

"SEC. 404O. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL DATA SECURITY FOR ENDEMIC FUNGAL DISEASE RESEARCH.

''(a) IN GENERAL.—The Director of NIH shall carry out a pilot program to conduct, support, and facilitate auditable research on endemic fungal disease. In carrying out such program, the Director of NIH shall—

''(1) award a grant to an eligible entity to install a blockchain on the servers of, or otherwise provide blockchain services to, the National Institutes of Health, and provide support with respect to such a blockchain, which shall contain public, unalterable data which includes every query made through the procedure established under subsection (c), as well as the identity of the individual who asked such a question, without disclosing the results of such queries;

''(2) award a grant to an eligible entity—

''(A) to provide to not less than 3 qualified hospitals qualified software; and

"(B) to provide customer service to each such hospital with respect to such qualified software or any associated service;

"(3) provide to such qualified hospitals any necessary hardware in accordance with subsection (e); and

"(4) award grants to eligible entities to test the cybersecurity of such qualified hospitals by attempting to attack simulated data on the servers of such hospitals.

"(b) ELIGIBLE ENTITIES; APPLICATION.—The Director of NIH shall determine whether an entity is eligible to receive a grant under this section and shall select hospitals to be qualified hospitals for purposes of this section. An entity seeking a grant under this section, and a hospital seeking to be so selected, shall submit to the Director of NIH an application in such form and manner and containing such information as the Director of NIH may specify.

"(c) DATA QUERIES.—The Director of NIH shall establish, for purposes of allowing researchers to process data from a qualified hospital's servers pursuant to this section, a procedure to determine—

"(1) who can ask queries of the servers;

''(2) which data the hospital must include on such servers; and

''(3) which questions may be asked of such servers, and what form of de-identification of the servers' data is required to ensure privacy.

''(d) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this section, the Director of NIH shall publish in the Federal Register a request for proposals for grants under paragraphs (1), (2), and (4) of subsection (a).

''(e) PROVISION OF SERVERS.—

''(1) IN GENERAL.—The Director of NIH shall, in carrying out subsection (a)(3), provide to qualified hospitals hardware, including computer servers, sufficient to support qualified software.

''(2) CONDITION.—As a condition on the receipt of a computer server under paragraph (1), a qualified hospital shall agree not to use the qualified software on the server to store data from patients of the hospital until the Director of NIH determines that testing performed pursuant to subsection (a)(4) has determined that simulated data used in such software could not be extracted from the hospital's servers.

''(f) DEFINITIONS.—In this section:

''(1) The term 'blockchain' means software that uses a distributed digital ledger of cryptographically signed transactions that are grouped into blocks, each of which—

''(A) is cryptographically linked to the previous block after validation and undergoing a consensus decision; and

''(B) when added as a new block, makes any older blocks more difficult to modify and is replicated across all copies of the ledger within the relevant network, with any conflicts in such blocks resolved automatically using established rules.

''(2) The term 'endemic fungal disease' means blastomycosis, coccidioidomycosis, histoplasmosis, and sporotrichosis.

''(3) The term 'qualified hospital' means a hospital that is located in a region in which endemic fungal disease is endemic.

''(4) The term 'qualified software' means software that uses secure multiparty encrypted computing to allow researchers to perform computations on encrypted data supplied by qualified hospitals.

''(5) The term 'secure multiparty encrypted computing' means a form of cryptography in which

parties can jointly compute a function of inputs while keeping those inputs private from each other, and from all other parties, such as multiparty homomorphic encryption, threshold encryption, and secure multiparty computation.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2021, to remain available until expended.''.

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