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115TH CONGRESS
2D SESSION

H. R. 6562

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

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2018

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

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A BILL

To support endemic orphan fungal disease research, incentivize Valley Fever 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 2018'' or the ''FORWARD Act of 2018''.

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

SEC. 2. FINDINGS.

Congress finds the following:

(1) Worldwide fungal infections, such as candidiasis, cryptococcosis, and aspergillosis, often pose fatal opportunistic threats to immunologically impaired persons.

(2) Endemic fungal infections, such as histoplasmosis, coccidioidomycosis, and blastomycosis, occur in certain geographic regions worldwide, including in the United States, and are acquired through exposure to the environment.

(3) Because the endemic mycoses referred to in paragraph (2) are regional, such endemic mycoses do not receive the same amount of resources as mycoses of worldwide distribution, even though within the regions in which they are endemic such strains pose significant public health threats.

(4) Coccidioidomycosis, also known as Valley Fever, is a fungal infection acquired by the inhalation of spores of certain fungi primarily found in the soil endemic to the American Southwest, including in Arizona, California, Nevada, New Mexico, Texas, Utah, and Washington.

(5) According to the Morbidity and Mortality Weekly Report issued by the Centers for Disease Control and Prevention and dated August 11, 2017—

(A) 97 percent of the all reported cases of Valley Fever occurred in California and Arizona;

(B) individuals at increased risk for severe Valley Fever include persons of African or Filipino descent, pregnant women, adults in older age groups, and other individuals with weakened immune systems;

(C) the overall incident rate of Valley Fever peaked in 2011 and again in 2016;

(D) in California, the Valley Fever incident rate for 2016 was the highest recorded to date, with 42 percent of cases reported coming from Kern County; and

(E) the reason for increases in Valley Fever cases reported in California in 2016 is not known.

(6) Valley Fever illness ranges from influenza-like symptoms to life-threatening when the infection spreads to other parts of the body, including the brain.

(7) The overall estimated impact of Valley Fever is less than 200,000 people in the United States, with roughly 200 deaths each year and over 11,000 new cases identified in 2016. The estimated economic impact to the United States is at least $500,000,000 from hospital, outpatient, and lost productivity costs.

(8) In the past 60 years, only 4 classes of antifungal compounds have been approved by the Food and Drug Administration for treatment for all fungal infections.

(9) Existing antifungal therapies often do not cure the fungal infection involved because, similar to how bacteria have become resistant to antibiotic therapies, some fungi no longer respond to the current limited antifungal therapies that are designed to treat them.

(10) Coccidioides, the cause of Valley Fever, is not cured by any available drug.

(11) Although antibiotic-resistant bacterial infections are a widely recognized public health threat, less is known about the effects of antifungal resistance and the burden of drug-resistant fungal infections.

(12) Fungal infections are a rising threat to public health and the resistance to current antifungal therapies will only complicate the Nation's response in the event of a public health emergency.

SEC. 3. CONTINUING SUPPORT FOR RESEARCH ON ENDEMIC ORPHAN FUNGAL DISEASES.

(a) IN GENERAL.—Subtitle F of title II of the 21st Century Cures Act (Public Law 114–255) is amended by inserting after section 2062 (42 U.S.C. 284s) the following new section:

"SEC. 2062A. ENDEMIC ORPHAN FUNGAL DISEASES.

''(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall continue to conduct or support epidemiological, basic, translational, and clinical research related to endemic orphan fungal diseases, including coccidioidomy-

cosis (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 of the Public Health Service Act (42 U.S.C. 283) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to endemic orphan fungal diseases, including Valley Fever.

''(c) VALLEY FEVER WORKING GROUP.—

''(1) ESTABLISHMENT.—The Secretary shall establish a working group, to be known as the Valley Fever Working Group (referred to in this section as the 'Working Group'), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to Valley Fever, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

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

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

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

"(ii) advances made pursuant to such research;

"(iii) Federal activities related to Valley Fever, including—

"(I) epidemiological activities related to Valley Fever; and

"(II) basic, clinical, and translational Valley Fever research related to the pathogenesis, prevention, diagnosis, and treatment of Valley Fever;

"(iv) gaps in Valley Fever 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 scientific 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 Valley Fever.

''(ii) Scientists or researchers with expertise.

''(iii) Patients and their family members.

''(iv) Nonprofit organizations that advocate for patients with respect to Valley Fever.

''(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 this Act, 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 this Act.

"(d) ENDEMIC ORPHAN FUNGAL DISEASE DEFINED.—The term 'endemic orphan fungal disease' has the meaning given such term in section 529B(a) of the Federal Food, Drug, and Cosmetic Act.".

(b) CONFORMING TABLE OF CONTENTS AMENDMENT.—Section 1(b) of the 21st Century Cures Act (Pub-

lic Law 114–255) is amended in the table of contents, by inserting after the item relating to section 2062 the following:

"Sec. 2062A. Endemic orphan fungal diseases.".

SEC. 4. ENDEMIC ORPHAN FUNGAL DISEASE FEDERAL-STATE MATCH PILOT PROGRAM.

(a) IN GENERAL.—For each of fiscal years 2019 through 2024, 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 respect to endemic orphan fungal diseases, including coccidioidomycosis.

(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)), or a nonprofit organization that has been provided funds from State or local government sources for epidemiological, basic, translational, and clinical research on endemic orphan fungal diseases during the 3-year period ending on the date of the enactment of this Act.

(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 ORPHAN FUNGAL DISEASE DEFINED.—The term ''endemic orphan fungal disease'' has the meaning given such term in section 529B of the Federal Food, Drug, and Cosmetic Act, as added by section 7.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $8,000,000 for each of fiscal years 2019 through 2024, to remain available until expended.

(g) SUNSET.—The Secretary may not award grants under this section on or after October 1, 2024.

SEC. 5. FDA GUIDANCE FOR INDUSTRY ON DEVELOPMENT OF DIAGNOSTICS AND ANTIFUNGAL DRUGS AND VACCINES FOR VALLEY FEVER.

(a) IN GENERAL.—Not later than one year 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) CONSULTATION.—In developing the draft guidance under subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall consult with institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), researchers, and other relevant stakeholders.

(c) FINAL GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance issued

under subsection (a) not later than 2 years after the date of the enactment of this Act.

SEC. 6. INCLUDING ANTIFUNGAL BIOLOGICAL PRODUCTS AS QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) IN GENERAL.—Section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(1) in subsection (a)—

(A) by inserting ''(or, pursuant to section 351 of the Public Health Service Act, in the case of an antifungal biological product)'' after ''pursuant to section 505 for a drug''; and

(B) by striking ''or the 7-year period described in section 527,'' and inserting ''the 7-year period described in section 527, or, in the case of an antifungal biological product, the 12-year period under section 351(k) of the Public Health Service Act,'';

(2) in subsection (c)—

(A) in paragraph (1), by inserting ''or, in the case of an antifungal biological product, section 351(a) of the Public Health Service Act'' after ''505(b)''; and

(B) in paragraph (2), by inserting ''or, in the case of an antifungal biological product, section 351 of the Public Health Service Act'' after ''505'';

(3) in subsection (d)(1) by inserting ''or, in the case of an antifungal biological product, section 351(a) of the Public Health Service Act'' after ''505(b)''; and

(4) in subsection (g), in the matter preceding paragraph (1)—

(A) by inserting ''(including antifungal biological products)'' after ''antifungal drug''; and

(B) by inserting ''or prevent'' after ''treat''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to applications for the approval of biological products under section 351 of the Public Health Service Act (42 U.S.C. 262) submitted on or after the date of the enactment of this Act.

(c) UPDATED GUIDANCE.—Not later than one year 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 update ''Qualified Infectious Disease Product Designation Questions and An-

swers Guidance for Industry'' issued in January 2018, to implement the amendments made by subsection (a).

SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR ENDEMIC ORPHAN FUNGAL DISEASES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by adding at the end the following new section:

''SEC. 529B. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR ENDEMIC ORPHAN FUNGAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) ENDEMIC ORPHAN FUNGAL DISEASE.—The term 'endemic orphan fungal disease' means a disease, such as coccidioidomycosis, that—

''(A) is caused by a fungus;

''(B) primarily occurs in certain limited geographic regions; and

''(C) is a rare disease or condition (as that term is defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2))).

''(2) ENDEMIC ORPHAN FUNGAL DISEASE DRUG APPLICATION.—The term 'endemic orphan fungal disease drug application' means an application that—

"(A) is a human drug application for a drug intended for use—

"(i) to prevent or treat harm from an endemic orphan fungal disease; or

"(ii) to cure an endemic orphan fungal disease;

"(B) the Secretary determines eligible for priority review;

"(C) is approved after the date of enactment of this section; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

"(3) HUMAN DRUG APPLICATION.—The term 'human drug application' has the meaning given such term in section 735(1).

"(4) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the let-

ters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

''(5) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of an endemic orphan fungal disease drug application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the endemic orphan fungal disease drug application.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of an endemic orphan fungal disease drug application upon approval by the Secretary of such endemic orphan fungal disease drug application.

''(2) TRANSFERABILITY.—The sponsor of a endemic orphan fungal disease drug application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the en-

demic orphan fungal disease drug application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

''(3) NOTIFICATION.—

''(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

''(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2019, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

''(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

''(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the

Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

''(1) The Secretary issues a priority review voucher under this section.

''(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher issued under this section.

''(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this Act with respect to such drug.

''(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.

''(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2024.''.

SEC. 8. INCLUDING ANTIFUNGAL PRODUCTS IN THE CARB–X PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall, in carrying out the Combating Antibiotic Resistant Bacteria Accelerator program of the Department of Health and Human Services (commonly referred to as ''CARB–X''), conduct research with respect to antifungal resistance, including therapies, diagnostics, and vaccines, including for coccidioidomycosis.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Biodefense Medical Countermeasure Development Fund established under section 319L(d) of the Public Health Service Act (42 U.S.C. 247d–7e(d)) to carry out subsection (a) $10,000,000 for each of fiscal years 2019 through 2024, to remain available until expended.

SEC. 9. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL DATA SECURITY FOR COCCIDIOIDOMYCOSIS 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 COCCIDIOIDOMYCOSIS RESEARCH.

''(a) IN GENERAL.—The Director of NIH shall carry out a pilot program to conduct, support, and facilitate auditable research on coccidioidomycosis (commonly referred to as 'Valley Fever'). In carrying out such program, the Director 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 'qualified hospital' means a hospital that is located in a region in which coccidioidomycosis is endemic.

"(3) 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.

"(4) 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 are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2020, to remain available until expended.''.

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