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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. MCCARTHY introduced the following bill; which was referred to the
Committee on _____

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) IN GENERAL.—This Act may be cited as the
5 “Finding Orphan-disease Remedies With Antifungal Re-
6 search and Development Act of 2019” or the “FOR-
7 WARD Act of 2019”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Continuing support for research on endemic fungal diseases.
- Sec. 3. Endemic fungal disease Federal-State match pilot program.
- Sec. 4. FDA guidance for industry on development of diagnostics and antifungal drugs and vaccines for Valley Fever.
- Sec. 5. Priority review; fast track product.
- Sec. 6. Priority review vouchers for products for prevention or treatment of endemic fungal diseases.
- Sec. 7. Establishment of antifungal resistance research program modeled on the CARB-X program.
- Sec. 8. Blockchain pilot program for hospital data security for endemic fungal disease research.

3 **SEC. 2. CONTINUING SUPPORT FOR RESEARCH ON EN-**
4 **DEMIC FUNGAL DISEASES.**

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

8 **“SEC. 320B. ENDEMIC FUNGAL DISEASES.**

9 “(a) IN GENERAL.—The Secretary shall continue to
10 conduct or support epidemiological, basic, translational,
11 and clinical research related to endemic fungal diseases,
12 including coccidioidomycosis (commonly known as and re-
13 ferred to in this section as ‘Valley Fever’).

14 “(b) REPORTS.—The Secretary shall ensure that
15 each triennial report under section 403 includes informa-
16 tion on actions undertaken by the National Institutes of
17 Health to carry out subsection (a) with respect to endemic
18 fungal diseases, including Valley Fever.

19 “(c) ENDEMIC FUNGAL DISEASE WORKING
20 GROUP.—

1 “(1) ESTABLISHMENT.—The Secretary shall es-
2 tablish a working group, to be known as the En-
3 demic Fungal Disease Working Group (referred to
4 in this section as the ‘Working Group’), comprised
5 of representatives of appropriate Federal agencies
6 and other non-Federal entities—

7 “(A) to provide expertise and to review all
8 efforts within the Department of Health and
9 Human Services related to endemic fungal dis-
10 ease;

11 “(B) to help ensure interagency coordina-
12 tion and minimize overlap with respect to such
13 disease; and

14 “(C) to examine research priorities with re-
15 spect to such disease.

16 “(2) RESPONSIBILITIES.—The Working Group
17 shall—

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

21 “(i) ongoing endemic fungal disease
22 research, including research related to
23 causes, prevention, treatment, surveillance,
24 diagnosis, diagnostics, duration of illness,

1 and intervention for individuals with an
2 endemic fungal disease;

3 “(ii) advances made pursuant to such
4 research;

5 “(iii) Federal activities related to en-
6 demic fungal disease, including—

7 “(I) epidemiological activities re-
8 lated to endemic fungal disease; and

9 “(II) basic, clinical, and
10 translational endemic fungal disease
11 research related to the pathogenesis,
12 prevention, diagnosis, and treatment
13 of endemic fungal disease;

14 “(iv) gaps in endemic fungal disease
15 research described in clause (iii)(II);

16 “(v) the Working Group’s meetings
17 required under paragraph (4); and

18 “(vi) the comments received by the
19 Working Group;

20 “(B) make recommendations to the Sec-
21 retary regarding any appropriate changes or
22 improvements to such activities and research;
23 and

24 “(C) solicit input from States, localities,
25 and nongovernmental entities, including organi-

1 zations representing patients, health care pro-
2 viders, researchers, and industry regarding sci-
3 entific advances, research questions, and sur-
4 veillance activities.

5 “(3) MEMBERSHIP.—The members of the
6 Working Group shall represent a diversity of sci-
7 entific disciplines and views and shall be composed
8 of the following members:

9 “(A) FEDERAL MEMBERS.—Seven Federal
10 members, consisting of one or more representa-
11 tives of each of the following:

12 “(i) The Office of the Assistant Sec-
13 retary for Health.

14 “(ii) The Food and Drug Administra-
15 tion.

16 “(iii) The Centers for Disease Control
17 and Prevention.

18 “(iv) The National Institutes of
19 Health.

20 “(v) Such other agencies and offices
21 of the Department of Health and Human
22 Services as the Secretary determines ap-
23 propriate.

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

4 “(i) Physicians and other medical pro-
5 viders with experience in diagnosing and
6 treating endemic fungal disease.

7 “(ii) Scientists or researchers with ex-
8 pertise.

9 “(iii) Patients and their family mem-
10 bers.

11 “(iv) Nonprofit organizations that ad-
12 vocate for patients with respect to endemic
13 fungal disease.

14 “(v) Other individuals whose expertise
15 is determined by the Secretary to be bene-
16 ficial to the functioning of the Working
17 Group.

18 “(4) MEETINGS.—The Working Group shall
19 meet annually.

20 “(5) REPORTING.—Not later than 2 years after
21 the date of enactment of the FORWARD Act of
22 2019, and every 2 years thereafter until termination
23 of the Working Group pursuant to paragraph (7),
24 the Working Group shall—

1 (1) GRANTS.—For each of fiscal years 2021
2 through 2025, the Secretary of Health and Human
3 Services shall, subject to the availability of appro-
4 priations, award grants through a competitive proc-
5 ess to eligible entities to conduct research with re-
6 spect to endemic fungal diseases, including coccidioi-
7 domycosis.

8 (2) PEER REVIEW.—Any research supported
9 under this section shall be subject to peer review in
10 accordance with the requirements applicable to re-
11 search supported by the National Institutes of
12 Health under section 492 of the Public Health Serv-
13 ice Act (42 U.S.C. 289a)

14 (b) ELIGIBILITY.—An entity eligible to receive a
15 grant under this section is a State or local public hospital,
16 an institution of higher education (as defined in section
17 101 of the Higher Education Act of 1965 (20 U.S.C.
18 1001)), a public health department, or a nonprofit organi-
19 zation that has been provided funds from State or local
20 government sources for epidemiological, basic,
21 translational, and clinical research on endemic fungal dis-
22 eases.

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

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

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

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

8 (d) AMOUNT OF GRANT.—The amount of a grant
9 under this section shall equal (to the extent practicable)
10 the amount of funds received from State or local govern-
11 ment sources for the research that is the subject of the
12 grant.

13 (e) ENDEMIC FUNGAL DISEASE DEFINED.—In this
14 section, the term “endemic fungal disease” means blasto-
15 mycosis, coccidioidomycosis, histoplasmosis, and
16 sporotrichosis.

17 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
18 authorized to be appropriated to carry out this section
19 \$8,000,000 for each of fiscal years 2021 through 2025,
20 to remain available until expended.

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

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

4 (a) DRAFT GUIDANCE.—Not later than 2 years after
5 the date of the enactment of this Act, the Secretary of
6 Health and Human Services, acting through the Commis-
7 sioner of Food and Drugs, shall issue draft guidance for
8 industry for the purposes of assisting entities seeking ap-
9 proval under the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 301 et seq.) or licensure under section 351
11 of the Public Health Service Act (42 U.S.C. 262) of
12 antifungal therapies, diagnostics, or vaccines, specifically
13 therapies, diagnostics, and vaccines designed to diagnose,
14 treat, or prevent coccidioidomycosis (commonly known as
15 Valley Fever).

16 (b) FINAL GUIDANCE.—Not later than 18 months
17 after the close of the public comment period on the draft
18 guidance issued pursuant to subsection (a), the Secretary
19 of Health and Human Services, acting through the Com-
20 missioner of Food and Drugs, shall finalize the draft guid-
21 ance.

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

1 **SEC. 5. PRIORITY REVIEW; FAST TRACK PRODUCT.**

2 (a) PRIORITY REVIEW.—

3 (1) IN GENERAL.—Section 524A(a) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 360n–1(a)) is amended by striking “then the Sec-
6 retary shall give priority review to the first applica-
7 tion submitted for approval for such drug under sec-
8 tion 505(b)” and inserting “or if the drug is a bio-
9 logical product intended to treat blastomycosis, coc-
10 cidoidomycosis, histoplasmosis, or sporotrichosis,
11 then the Secretary shall give priority review to the
12 first application submitted for approval for such
13 drug under section 505(b) of this Act or section
14 351(a) of the Public Health Service Act”.

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

21 (b) FAST TRACK PRODUCT.—Section 506(b)(1) of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 356(b)(1)) is amended by striking “or if the Secretary
24 designates the drug as a qualified infectious disease prod-
25 uct under section 505E(d)” and inserting “if the Sec-
26 retary designates the drug as a qualified infectious disease

1 product under section 505E(d), or if the drug is a biologi-
2 cal product intended to treat blastomycosis, coccidioidomy-
3 cosis, histoplasmosis, or sporotrichosis”.

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

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

9 (1) by redesignating subparagraph (S) as sub-
10 paragraph (T); and

11 (2) by inserting after subparagraph (R) the fol-
12 lowing:

13 “(S) Blastomycosis, coccidioidomycosis,
14 histoplasmosis, and sporotrichosis.”.

15 **SEC. 7. ESTABLISHMENT OF ANTIFUNGAL RESISTANCE RE-**
16 **SEARCH PROGRAM MODELED ON THE CARB-**
17 **X PROGRAM.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services, acting through the Director of the Bio-
20 medical Advanced Research and Development Authority,
21 shall carry out a program, modeled on the Combating An-
22 tibiotic Resistant Bacteria Accelerator program of the De-
23 partment of Health and Human Services (commonly re-
24 ferred to as “CARB-X”), for research with respect to

1 antifungal resistance, including therapies, diagnostics, and
2 vaccines, including for coccidioidomycosis.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
4 authorized to be appropriated to carry out subsection (a)
5 \$10,000,000 for each of fiscal years 2021 through 2025,
6 to remain available until expended.

7 **SEC. 8. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**
8 **DATA SECURITY FOR ENDEMIC FUNGAL DIS-**
9 **EASE RESEARCH.**

10 Part A of title IV of the Public Health Service Act
11 (42 U.S.C. 281 et seq.) is amended by adding at the end
12 the following new section:

13 **“SEC. 404O. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**
14 **DATA SECURITY FOR ENDEMIC FUNGAL DIS-**
15 **EASE RESEARCH.**

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

20 “(1) award a grant to an eligible entity to in-
21 stall a blockchain on the servers of, or otherwise pro-
22 vide blockchain services to, the National Institutes of
23 Health, and provide support with respect to such a
24 blockchain, which shall contain public, unalterable
25 data which includes every query made through the

1 procedure established under subsection (c), as well
2 as the identity of the individual who asked such a
3 question, without disclosing the results of such que-
4 ries;

5 “(2) award a grant to an eligible entity—

6 “(A) to provide to not less than 3 qualified
7 hospitals qualified software; and

8 “(B) to provide customer service to each
9 such hospital with respect to such qualified
10 software or any associated service;

11 “(3) provide to such qualified hospitals any nec-
12 essary hardware in accordance with subsection (e);
13 and

14 “(4) award grants to eligible entities to test the
15 cybersecurity of such qualified hospitals by attempt-
16 ing to attack simulated data on the servers of such
17 hospitals.

18 “(b) ELIGIBLE ENTITIES; APPLICATION.—The Di-
19 rector of NIH shall determine whether an entity is eligible
20 to receive a grant under this section and shall select hos-
21 pitals to be qualified hospitals for purposes of this section.
22 An entity seeking a grant under this section, and a hos-
23 pital seeking to be so selected, shall submit to the Director
24 of NIH an application in such form and manner and con-

1 taining such information as the Director of NIH may
2 specify.

3 “(c) DATA QUERIES.—The Director of NIH shall es-
4 tablish, for purposes of allowing researchers to process
5 data from a qualified hospital’s servers pursuant to this
6 section, a procedure to determine—

7 “(1) who can ask queries of the servers;

8 “(2) which data the hospital must include on
9 such servers; and

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

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

18 “(e) PROVISION OF SERVERS.—

19 “(1) IN GENERAL.—The Director of NIH shall,
20 in carrying out subsection (a)(3), provide to quali-
21 fied hospitals hardware, including computer servers,
22 sufficient to support qualified software.

23 “(2) CONDITION.—As a condition on the receipt
24 of a computer server under paragraph (1), a quali-
25 fied hospital shall agree not to use the qualified soft-

1 ware on the server to store data from patients of the
2 hospital until the Director of NIH determines that
3 testing performed pursuant to subsection (a)(4) has
4 determined that simulated data used in such soft-
5 ware could not be extracted from the hospital’s serv-
6 ers.

7 “(f) DEFINITIONS.—In this section:

8 “(1) The term ‘blockchain’ means software that
9 uses a distributed digital ledger of cryptographically
10 signed transactions that are grouped into blocks,
11 each of which—

12 “(A) is cryptographically linked to the pre-
13 vious block after validation and undergoing a
14 consensus decision; and

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

21 “(2) The term ‘endemic fungal disease’ means
22 blastomycosis, coccidioidomycosis, histoplasmosis,
23 and sporotrichosis.

1 “(3) The term ‘qualified hospital’ means a hos-
2 pital that is located in a region in which endemic
3 fungal disease is endemic.

4 “(4) The term ‘qualified software’ means soft-
5 ware that uses secure multiparty encrypted com-
6 puting to allow researchers to perform computations
7 on encrypted data supplied by qualified hospitals.

8 “(5) The term ‘secure multiparty encrypted
9 computing’ means a form of cryptography in which
10 parties can jointly compute a function of inputs
11 while keeping those inputs private from each other,
12 and from all other parties, such as multiparty homo-
13 morphic encryption, threshold encryption, and secure
14 multiparty computation.

15 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
16 is authorized to be appropriated to carry out this section
17 \$5,000,000 for fiscal year 2021, to remain available until
18 expended.”.