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

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".

8 (b) TABLE OF CONTENTS.—The table of contents for

9 this Act is as follows:

SEC. 2. CONTINUING SUPPORT FOR RESEARCH ON EN-DEMIC 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-

1 demic Fungal Disease Working Group (referred to

2 in this section as the 'Working Group'), comprised

3 of representatives of appropriate Federal agencies

4 and other non-Federal entities—

5   "(A) to provide expertise and to review all

6   efforts within the Department of Health and

7   Human Services related to endemic fungal dis-

8   ease;

9   "(B) to help ensure interagency coordina-

10   tion and minimize overlap with respect to such

11   disease; and

12   "(C) to examine research priorities with re-

13   spect to such disease.

14   "(2) RESPONSIBILITIES.—The Working Group

15 shall—

16   "(A) not later than 2 years after the date

17   of enactment of the FORWARD Act of 2019,

18   develop or update a summary of—

19   "(i) ongoing endemic fungal disease

20   research, including research related to

21   causes, prevention, treatment, surveillance,

22   diagnosis, diagnostics, duration of illness,

23   and intervention for individuals with an

24   endemic fungal disease;

1 　　　　　"(ii) advances made pursuant to such

2 　　　research;

3 　　　　　"(iii) Federal activities related to en-

4 　　　demic fungal disease, including—

5 　　　　　　　"(I) epidemiological activities re-

6 　　　　　lated to endemic fungal disease; and

7 　　　　　　　"(II) basic, clinical, and transla-

8 　　　　　tional endemic fungal disease research

9 　　　　　related to the pathogenesis, preven-

10 　　　　　tion, diagnosis, and treatment of en-

11 　　　　　demic fungal disease;

12 　　　　　"(iv) gaps in endemic fungal disease

13 　　　research described in clause (iii)(II);

14 　　　　　"(v) the Working Group's meetings

15 　　　required under paragraph (4); and

16 　　　　　"(vi) the comments received by the

17 　　　Working Group;

18 　　　"(B) make recommendations to the Sec-

19 　　retary regarding any appropriate changes or

20 　　improvements to such activities and research;

21 　　and

22 　　　"(C) solicit input from States, localities,

23 　　and nongovernmental entities, including organi-

24 　　zations representing patients, health care pro-

25 　　viders, researchers, and industry regarding sci-

1 entific advances, research questions, and sur-
2 veillance activities.

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

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

10   "(i) The Office of the Assistant Sec-
11   retary for Health.

12   "(ii) The Food and Drug Administra-
13   tion.

14   "(iii) The Centers for Disease Control
15   and Prevention.

16   "(iv) The National Institutes of
17   Health.

18   "(v) Such other agencies and offices
19   of the Department of Health and Human
20   Services as the Secretary determines ap-
21   propriate.

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

1   "(i) Physicians and other medical pro-

2   viders with experience in diagnosing and

3   treating endemic fungal disease.

4   "(ii) Scientists or researchers with ex-

5   pertise.

6   "(iii) Patients and their family mem-

7   bers.

8   "(iv) Nonprofit organizations that ad-

9   vocate for patients with respect to endemic

10   fungal disease.

11   "(v) Other individuals whose expertise

12   is determined by the Secretary to be bene-

13   ficial to the functioning of the Working

14   Group.

15   "(4) MEETINGS.—The Working Group shall

16 meet annually.

17   "(5) REPORTING.—Not later than 2 years after

18 the date of enactment of the FORWARD Act of

19 2019, and every 2 years thereafter until termination

20 of the Working Group pursuant to paragraph (7),

21 the Working Group shall—

22   "(A) submit a report on its activities under

23   paragraph (2)(A) and any recommendations

24   under paragraph (2)(B) to the Secretary, the

25   Committee on Energy and Commerce of the

1 House of Representatives, and the Committee

2 on Health, Education, Labor, and Pensions of

3 the Senate; and

4 "(B) make such report publicly available

5 on the internet website of the Department of

6 Health and Human Services.

7 "(6) APPLICABILITY OF FACA.—The Working

8 Group shall be treated as an advisory committee

9 subject to the Federal Advisory Committee Act (5

10 U.S.C. App.).

11 "(7) SUNSET.—The Working Group under this

12 section shall terminate 5 years after the date of en-

13 actment of the FORWARD Act of 2019.

14 "(d) ENDEMIC FUNGAL DISEASE DEFINED.—In this

15 section, the term 'endemic fungal disease' means blasto-

16 mycosis, coccidioidomycosis, histoplasmosis, and sporotri-

17 chosis.".

18 **SEC. 3. ENDEMIC FUNGAL DISEASE FEDERAL-STATE**

19 **MATCH PILOT PROGRAM.**

20 (a) IN GENERAL.—

21 (1) GRANTS.—For each of fiscal years 2021

22 through 2025, the Secretary of Health and Human

23 Services shall, subject to the availability of appro-

24 priations, award grants through a competitive proc-

25 ess to eligible entities to conduct research with re-

1 spect to endemic fungal diseases, including coccidioi-

2 domycosis.

3   (2) PEER REVIEW.—Any research supported

4 under this section shall be subject to peer review in

5 accordance with the requirements applicable to re-

6 search supported by the National Institutes of

7 Health under section 492 of the Public Health Serv-

8 ice Act (42 U.S.C. 289a).

9   (b) ELIGIBILITY.—An entity eligible to receive a

10 grant under this section is a State or local public hospital,

11 an institution of higher education (as defined in section

12 101 of the Higher Education Act of 1965 (20 U.S.C.

13 1001)), a public health department, or a nonprofit organi-

14 zation that has been provided funds from State or local

15 government sources for epidemiological, basic, translation-

16 al, and clinical research on endemic fungal diseases.

17   (c) APPLICATION.—An entity seeking a grant under

18 this section shall submit an application to the Secretary—

19   (1) in such form and manner as the Secretary

20 shall prescribe;

21   (2) that contains a certification that the entity

22 has received the funds described in subsection (b)

23 and that specifies the amount of such funds; and

24   (3) that contains such other information as the

25 Secretary may require.

1 (d) AMOUNT OF GRANT.—The amount of a grant

2 under this section shall equal (to the extent practicable)

3 the amount of funds received from State or local govern-

4 ment sources for the research that is the subject of the

5 grant.

6 (e) ENDEMIC FUNGAL DISEASE DEFINED.—In this

7 section, the term "endemic fungal disease" means blasto-

8 mycosis, coccidioidomycosis, histoplasmosis, and sporotri-

9 chosis.

10 (f) AUTHORIZATION OF APPROPRIATIONS.—There is

11 authorized to be appropriated to carry out this section

12 $8,000,000 for each of fiscal years 2021 through 2025,

13 to remain available until expended.

14 (g) SUNSET.—The Secretary may not award grants

15 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.

19 (a) DRAFT GUIDANCE.—Not later than 2 years after

20 the date of the enactment of this Act, the Secretary of

21 Health and Human Services, acting through the Commis-

22 sioner of Food and Drugs, shall issue draft guidance for

23 industry for the purposes of assisting entities seeking ap-

24 proval under the Federal Food, Drug, and Cosmetic Act

25 (21 U.S.C. 301 et seq.) or licensure under section 351

1 of the Public Health Service Act (42 U.S.C. 262) of

2 antifungal therapies, diagnostics, or vaccines, specifically

3 therapies, diagnostics, and vaccines designed to diagnose,

4 treat, or prevent coccidioidomycosis (commonly known as

5 Valley Fever).

6 (b) FINAL GUIDANCE.—Not later than 18 months

7 after the close of the public comment period on the draft

8 guidance issued pursuant to subsection (a), the Secretary

9 of Health and Human Services, acting through the Com-

10 missioner of Food and Drugs, shall finalize the draft guid-

11 ance.

12 (c) WORKSHOPS; GOOD GUIDANCE PRACTICES.—In

13 developing and issuing the guidance required by this sec-

14 tion, the Secretary of Health and Human Services shall

15 hold at least 2 public workshops.

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

17 (a) PRIORITY REVIEW.—

18 (1) IN GENERAL.—Section 524A(a) of the Fed-

19 eral Food, Drug, and Cosmetic Act (21 U.S.C.

20 360n–1(a)) is amended by striking "then the Sec-

21 retary shall give priority review to the first applica-

22 tion submitted for approval for such drug under sec-

23 tion 505(b)" and inserting "or if the drug is a bio-

24 logical product intended to treat blastomycosis, coc-

25 cidioidomycosis, histoplasmosis, or sporotrichosis,

1 then the Secretary shall give priority review to the

2 first application submitted for approval for such

3 drug under section 505(b) of this Act or section

4 351(a) of the Public Health Service Act''.

5 (2) APPLICABILITY.—The amendment made by

6 paragraph (1) applies to an application submitted

7 under section 351(a) of the Public Health Service

8 Act (42 U.S.C. 262(a)) only if such application is

9 submitted on or after the date of enactment of this

10 Act.

11 (b) FAST TRACK PRODUCT.—Section 506(b)(1) of

12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

13 356(b)(1)) is amended by striking ''or if the Secretary

14 designates the drug as a qualified infectious disease prod-

15 uct under section 505E(d)'' and inserting ''if the Sec-

16 retary designates the drug as a qualified infectious disease

17 product under section 505E(d), or if the drug is a biologi-

18 cal product intended to treat blastomycosis, coccidioidomy-

19 cosis, histoplasmosis, or sporotrichosis''.

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

23 Section 524(a)(3) of the Federal Food, Drug, and

24 Cosmetic Act (21 U.S.C. 360n(a)(3)) is amended—

1   (1) by redesignating subparagraph (S) as sub-

2 paragraph (T); and

3   (2) by inserting after subparagraph (R) the fol-

4 lowing:

5   "(S) Blastomycosis, coccidioidomycosis,

6   histoplasmosis, and sporotrichosis.".

7 **SEC. 7. ESTABLISHMENT OF ANTIFUNGAL RESISTANCE RE-**

8   **SEARCH PROGRAM MODELED ON THE CARB–**

9   **X PROGRAM.**

10   (a) IN GENERAL.—The Secretary of Health and

11 Human Services, acting through the Director of the Bio-

12 medical Advanced Research and Development Authority,

13 shall carry out a program, modeled on the Combating An-

14 tibiotic Resistant Bacteria Accelerator program of the De-

15 partment of Health and Human Services (commonly re-

16 ferred to as "CARB–X"), for research with respect to

17 antifungal resistance, including therapies, diagnostics, and

18 vaccines, including for coccidioidomycosis.

19   (b) AUTHORIZATION OF APPROPRIATIONS.—There is

20 authorized to be appropriated to carry out subsection (a)

21 $10,000,000 for each of fiscal years 2021 through 2025,

22 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

1 "(B) to provide customer service to each

2 such hospital with respect to such qualified

3 software or any associated service;

4 "(3) provide to such qualified hospitals any nec-

5 essary hardware in accordance with subsection (e);

6 and

7 "(4) award grants to eligible entities to test the

8 cybersecurity of such qualified hospitals by attempt-

9 ing to attack simulated data on the servers of such

10 hospitals.

11 "(b) ELIGIBLE ENTITIES; APPLICATION.—The Di-

12 rector of NIH shall determine whether an entity is eligible

13 to receive a grant under this section and shall select hos-

14 pitals to be qualified hospitals for purposes of this section.

15 An entity seeking a grant under this section, and a hos-

16 pital seeking to be so selected, shall submit to the Director

17 of NIH an application in such form and manner and con-

18 taining such information as the Director of NIH may

19 specify.

20 "(c) DATA QUERIES.—The Director of NIH shall es-

21 tablish, for purposes of allowing researchers to process

22 data from a qualified hospital's servers pursuant to this

23 section, a procedure to determine—

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

1   ''(2) which data the hospital must include on

2   such servers; and

3   ''(3) which questions may be asked of such

4   servers, and what form of de-identification of the

5   servers' data is required to ensure privacy.

6   ''(d) REQUEST FOR PROPOSALS.—Not later than 90

7   days after the date of the enactment of this section, the

8   Director of NIH shall publish in the Federal Register a

9   request for proposals for grants under paragraphs (1), (2),

10 and (4) of subsection (a).

11 ''(e) PROVISION OF SERVERS.—

12   ''(1) IN GENERAL.—The Director of NIH shall,

13 in carrying out subsection (a)(3), provide to quali-

14 fied hospitals hardware, including computer servers,

15 sufficient to support qualified software.

16   ''(2) CONDITION.—As a condition on the receipt

17 of a computer server under paragraph (1), a quali-

18 fied hospital shall agree not to use the qualified soft-

19 ware on the server to store data from patients of the

20 hospital until the Director of NIH determines that

21 testing performed pursuant to subsection (a)(4) has

22 determined that simulated data used in such soft-

23 ware could not be extracted from the hospital's serv-

24 ers.

25 ''(f) DEFINITIONS.—In this section:

1 "(1) The term 'blockchain' means software that

2 uses a distributed digital ledger of cryptographically

3 signed transactions that are grouped into blocks,

4 each of which—

5   "(A) is cryptographically linked to the pre-

6   vious block after validation and undergoing a

7   consensus decision; and

8   "(B) when added as a new block, makes

9   any older blocks more difficult to modify and is

10   replicated across all copies of the ledger within

11   the relevant network, with any conflicts in such

12   blocks resolved automatically using established

13   rules.

14 "(2) The term 'endemic fungal disease' means

15 blastomycosis, coccidioidomycosis, histoplasmosis,

16 and sporotrichosis.

17 "(3) The term 'qualified hospital' means a hos-

18 pital that is located in a region in which endemic

19 fungal disease is endemic.

20 "(4) The term 'qualified software' means soft-

21 ware that uses secure multiparty encrypted com-

22 puting to allow researchers to perform computations

23 on encrypted data supplied by qualified hospitals.

24 "(5) The term 'secure multiparty encrypted

25 computing' means a form of cryptography in which

1   parties can jointly compute a function of inputs

2   while keeping those inputs private from each other,

3   and from all other parties, such as multiparty homo-

4   morphic encryption, threshold encryption, and secure

5   multiparty computation.

6   ''(g) AUTHORIZATION OF APPROPRIATIONS.—There

7 is authorized to be appropriated to carry out this section

8 $5,000,000 for fiscal year 2021, to remain available until

9 expended.''.

○