

116TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

\_\_\_\_\_  
IN THE SENATE OF THE UNITED STATES

\_\_\_\_\_  
\_\_\_\_\_ introduced the following bill; which was read twice  
and 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”.

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

## 2

- 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.

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

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

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

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

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

17 “(c) ENDEMIC FUNGAL DISEASE WORKING  
 18 GROUP.—

19 “(1) ESTABLISHMENT.—The Secretary shall es-  
 20 tablish 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  
8 translational endemic fungal disease  
9 research related to the pathogenesis,  
10 prevention, diagnosis, and treatment  
11 of endemic 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  
17 sparotrichosis.”.

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,  
16      translational, and clinical research on endemic fungal dis-  
17      eases.

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

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

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



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

3       (d) AMOUNT OF GRANT.—The amount of a grant  
4       under this section shall equal (to the extent practicable)  
5       the amount of funds received from State or local govern-  
6       ment sources for the research that is the subject of the  
7       grant.

8       (e) ENDEMIC FUNGAL DISEASE DEFINED.—In this  
9       section, the term “endemic fungal disease” means blasto-  
10      mycosis,      coccidioidomycosis,      histoplasmosis,      and  
11      sporotrichosis.

12      (f) AUTHORIZATION OF APPROPRIATIONS.—There is  
13      authorized to be appropriated to carry out this section  
14      \$8,000,000 for each of fiscal years 2021 through 2025,  
15      to remain available until expended.

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

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

21      (a) DRAFT GUIDANCE.—Not later than 2 years after  
22      the date of the enactment of this Act, the Secretary of  
23      Health and Human Services, acting through the Commis-  
24      sioner of Food and Drugs, shall issue draft guidance for  
25      industry for the purposes of assisting entities seeking ap-

1 proval under the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 301 et seq.) or licensure under section 351  
3 of the Public Health Service Act (42 U.S.C. 262) of  
4 antifungal therapies, diagnostics, or vaccines, specifically  
5 therapies, diagnostics, and vaccines designed to diagnose,  
6 treat, or prevent coccidioidomycosis (commonly known as  
7 Valley Fever).

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

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

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

19 (a) PRIORITY REVIEW.—

20 (1) IN GENERAL.—Section 524A(a) of the Fed-  
21 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
22 360n–1(a)) is amended by striking “then the Sec-  
23 retary shall give priority review to the first applica-  
24 tion submitted for approval for such drug under sec-  
25 tion 505(b)” and inserting “or if the drug is a bio-

1       logical product intended to treat blastomycosis, coc-  
2       cidioidomycosis, histoplasmosis, or sporotrichosis,  
3       then the Secretary shall give priority review to the  
4       first application submitted for approval for such  
5       drug under section 505(b) of this Act or section  
6       351(a) of the Public Health Service Act”.

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

13      (b) FAST TRACK PRODUCT.—Section 506(b)(1) of  
14      the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15      356(b)(1)) is amended by striking “or if the Secretary  
16      designates the drug as a qualified infectious disease prod-  
17      uct under section 505E(d)” and inserting “, if the Sec-  
18      retary designates the drug as a qualified infectious disease  
19      product under section 505E(d), or if the drug is a biologi-  
20      cal product intended to treat blastomycosis, coccidioidomy-  
21      cosis, histoplasmosis, or sporotrichosis”.

1 **SEC. 6. PRIORITY REVIEW VOUCHERS FOR PRODUCTS FOR**  
2 **PREVENTION OR TREATMENT OF ENDEMIC**  
3 **FUNGAL DISEASES.**

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

6 (1) by redesignating subparagraph (S) as sub-  
7 paragraph (T); and

8 (2) by inserting after subparagraph (R) the fol-  
9 lowing:

10 “(S) Blastomycosis, coccidioidomycosis,  
11 histoplasmosis, and sporotrichosis.”.

12 **SEC. 7. ESTABLISHMENT OF ANTIFUNGAL RESISTANCE RE-**  
13 **SEARCH PROGRAM MODELED ON THE CARB-**  
14 **X PROGRAM.**

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

24 (b) AUTHORIZATION OF APPROPRIATIONS.—There is  
25 authorized to be appropriated to carry out subsection (a)

1 \$10,000,000 for each of fiscal years 2021 through 2025,  
2 to remain available until expended.

3 **SEC. 8. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**  
4 **DATA SECURITY FOR ENDEMIC FUNGAL DIS-**  
5 **EASE RESEARCH.**

6 Part A of title IV of the Public Health Service Act  
7 (42 U.S.C. 281 et seq.) is amended by adding at the end  
8 the following new section:

9 **“SEC. 404O. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**  
10 **DATA SECURITY FOR ENDEMIC FUNGAL DIS-**  
11 **EASE RESEARCH.**

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

16 “(1) award a grant to an eligible entity to in-  
17 stall a blockchain on the servers of, or otherwise pro-  
18 vide blockchain services to, the National Institutes of  
19 Health, and provide support with respect to such a  
20 blockchain, which shall contain public, unalterable  
21 data which includes every query made through the  
22 procedure established under subsection (c), as well  
23 as the identity of the individual who asked such a  
24 question, without disclosing the results of such que-  
25 ries;

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

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

4 “(B) to provide customer service to each  
5 such hospital with respect to such qualified  
6 software or any associated service;

7 “(3) provide to such qualified hospitals any nec-  
8 essary hardware in accordance with subsection (e);  
9 and

10 “(4) award grants to eligible entities to test the  
11 cybersecurity of such qualified hospitals by attempt-  
12 ing to attack simulated data on the servers of such  
13 hospitals.

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

23 “(c) DATA QUERIES.—The Director of NIH shall es-  
24 tablish, for purposes of allowing researchers to process

1 data from a qualified hospital's servers pursuant to this  
2 section, a procedure to determine—

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

4 “(2) which data the hospital must include on  
5 such servers; and

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

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

14 “(e) PROVISION OF SERVERS.—

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

19 “(2) CONDITION.—As a condition on the receipt  
20 of a computer server under paragraph (1), a quali-  
21 fied hospital shall agree not to use the qualified soft-  
22 ware on the server to store data from patients of the  
23 hospital until the Director of NIH determines that  
24 testing performed pursuant to subsection (a)(4) has  
25 determined that simulated data used in such soft-

1       ware could not be extracted from the hospital’s serv-  
2       ers.

3       “(f) DEFINITIONS.—In this section:

4               “(1) The term ‘blockchain’ means software that  
5       uses a distributed digital ledger of cryptographically  
6       signed transactions that are grouped into blocks,  
7       each of which—

8               “(A) is cryptographically linked to the pre-  
9       vious block after validation and undergoing a  
10       consensus decision; and

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

17              “(2) The term ‘endemic fungal disease’ means  
18       blastomycosis, coccidioidomycosis, histoplasmosis,  
19       and sporotrichosis.

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

23              “(4) The term ‘qualified software’ means soft-  
24       ware that uses secure multiparty encrypted com-



1       puting to allow researchers to perform computations  
2       on encrypted data supplied by qualified hospitals.

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

10       “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
11       is authorized to be appropriated to carry out this section  
12       \$5,000,000 for fiscal year 2021, to remain available until  
13       expended.”.