

117TH CONGRESS  
1ST SESSION

# H. R. 5566

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

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 12, 2021

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

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## A BILL

To support 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 2021” or the “FOR-  
7 WARD Act of 2021”.

8 (b) TABLE OF CONTENTS.—The table of contents for  
9 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 Working Group.  
 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 to encourage treatments and vaccines for Valley Fever.  
 Sec. 7. Combating Antimicrobial Resistance Biopharmaceutical Accelerator Program.

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 447C of such Act (42 U.S.C. 285f-4)  
 5 the following new section:

6 **“SEC. 447D. ENDEMIC FUNGAL DISEASES.**

7 “(a) IN GENERAL.—The Director of the Institute  
 8 shall—

9 “(1) continue to conduct or support epidemio-  
 10 logical, basic, translational, and clinical research,  
 11 such as vaccine development, related to endemic  
 12 fungal diseases, including coccidioidomycosis (com-  
 13 monly known as and referred to in this section as  
 14 ‘Valley Fever’); and

15 “(2) subject to the availability of appropria-  
 16 tions, make grants to, or enter into contracts with,  
 17 public or nonprofit private entities to conduct such  
 18 research.

19 “(b) REPORTS.—The Director of the Institute shall  
 20 ensure that each triennial report under section 403 in-

1 cludes information on actions undertaken by the National  
2 Institutes of Health to carry out subsection (a) with re-  
3 spect to endemic fungal diseases, including Valley Fever.

4 “(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-  
5 dition to other amounts available for the purposes of car-  
6 rying out this section, there is authorized to be appro-  
7 priated to carry out this section \$20,000,000 for each of  
8 fiscal years 2022 through 2026 for such purpose.”.

9 **SEC. 3. ENDEMIC FUNGAL DISEASE WORKING GROUP.**

10 (a) ESTABLISHMENT.—The Secretary of Health and  
11 Human Services (in this section referred to as the “Sec-  
12 retary”) shall establish a working group, to be known as  
13 the Endemic Fungal Disease Working Group (referred to  
14 in this section as the “Working Group”), comprised of  
15 representatives of appropriate Federal agencies and other  
16 non-Federal entities—

17 (1) to provide expertise and to review all efforts  
18 within the Department of Health and Human Serv-  
19 ices related to endemic fungal disease;

20 (2) to help ensure interagency coordination and  
21 minimize overlap with respect to such disease; and

22 (3) to examine research priorities with respect  
23 to such disease.

24 (b) RESPONSIBILITIES.—The Working Group shall—

1           (1) not later than 2 years after the date of en-  
2           actment of this Act, develop or update a summary  
3           of—

4                   (A) ongoing endemic fungal disease re-  
5                   search, including research related to causes,  
6                   prevention (such as vaccine development), treat-  
7                   ment, surveillance, diagnosis, diagnostics, dura-  
8                   tion of illness, and intervention for individuals  
9                   with an endemic fungal disease;

10                   (B) advances made pursuant to such re-  
11                   search;

12                   (C) the impact of viral respiratory ill-  
13                   nesses, including COVID–19, and fungal lung  
14                   diseases and pneumonias;

15                   (D) Federal activities related to endemic  
16                   fungal disease, including—

17                           (i) epidemiological activities related to  
18                           endemic fungal disease; and

19                           (ii) basic, clinical, and translational  
20                           endemic fungal disease research related to  
21                           the pathogenesis, prevention (such as vac-  
22                           cine development), diagnosis, and treat-  
23                           ment of endemic fungal disease;

24                   (E) gaps in endemic fungal disease re-  
25                   search described in subparagraph (D)(ii);

1 (F) the Working Group's meetings re-  
2 quired under subsection (d); and

3 (G) the comments received by the Working  
4 Group;

5 (2) make recommendations, including a pro-  
6 posed strategy related to development of thera-  
7apeutics and vaccines, to the Secretary regarding any  
8 appropriate changes or improvements related to ac-  
9tivities described in paragraph (1); and

10 (3) in implementing this subsection, solicit  
11 input from States, localities, and nongovernmental  
12 entities, including organizations representing pa-  
13tients, health care providers, researchers, and indus-  
14try regarding scientific advances, research questions,  
15and surveillance activities.

16 (c) MEMBERSHIP.—The members of the Working  
17 Group shall represent a diversity of scientific disciplines  
18 and views and shall be composed of the following mem-  
19 bers:

20 (1) FEDERAL MEMBERS.—Seven Federal mem-  
21 bers, consisting of one or more representatives of  
22 each of the following:

23 (A) The Office of the Assistant Secretary  
24 for Health.

25 (B) The Food and Drug Administration.

1 (C) The Centers for Disease Control and  
2 Prevention.

3 (D) The National Institutes of Health.

4 (E) Such other agencies and offices of the  
5 Department of Health and Human Services as  
6 the Secretary determines appropriate.

7 (2) NON-FEDERAL PUBLIC MEMBERS.—Seven  
8 non-Federal public members, consisting of represent-  
9 atives of the following categories:

10 (A) Physicians and other medical providers  
11 with experience in diagnosing and treating en-  
12 demic fungal disease.

13 (B) Scientists or researchers with exper-  
14 tise.

15 (C) Patients and their family members.

16 (D) Nonprofit organizations that advocate  
17 for patients with respect to endemic fungal dis-  
18 ease.

19 (E) Other individuals whose expertise is  
20 determined by the Secretary to be beneficial to  
21 the functioning of the Working Group.

22 (d) MEETINGS.—The Working Group shall meet an-  
23 nually.

24 (e) REPORTING.—Not later than 2 years after the  
25 date of enactment of this Act, and every 2 years thereafter

1 until termination of the Working Group pursuant to sub-  
2 section (g), the Working Group shall—

3           (1) submit a report on its activities under sub-  
4 section (b)(1) and any recommendations under sub-  
5 section (b)(2) to the Secretary, the Committee on  
6 Energy and Commerce of the House of Representa-  
7 tives, and the Committee on Health, Education,  
8 Labor, and Pensions of the Senate; and

9           (2) make such report publicly available on the  
10 internet website of the Department of Health and  
11 Human Services.

12       (f) APPLICABILITY OF FACCA.—The Working Group  
13 shall be treated as an advisory committee subject to the  
14 Federal Advisory Committee Act (5 U.S.C. App.).

15       (g) SUNSET.—The Working Group under this section  
16 shall terminate 5 years after the date of enactment of this  
17 Act.

18       (h) ENDEMIC FUNGAL DISEASE DEFINED.—In this  
19 section, the term “endemic fungal disease” means blasto-  
20 mycosis, coccidioidomycosis, histoplasmosis, and  
21 sporotrichosis.

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 coccidioidomycosis,  
10 then the Secretary shall give priority review to the  
11 first application submitted for approval for such  
12 drug under section 505(b) of this Act or section  
13 351(a) of the Public Health Service Act”.

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

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

3 **SEC. 6. PRIORITY REVIEW VOUCHERS TO ENCOURAGE**  
4 **TREATMENTS AND VACCINES FOR VALLEY**  
5 **FEVER.**

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

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

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

12 “(S) Coccidioidomycosis.”

13 **SEC. 7. COMBATING ANTIMICROBIAL RESISTANCE BIO-**  
14 **PHARMACEUTICAL ACCELERATOR PROGRAM.**

15 Paragraph (4) of section 319L(c) of the Public  
16 Health Service Act (42 U.S.C. 247d–7e(c)) is amended  
17 by adding at the end the following:

18 “(G) COMBATING ANTIMICROBIAL RESIST-  
19 ANCE BIOPHARMACEUTICAL ACCELERATOR PRO-  
20 GRAM.—

21 “(i) IN GENERAL.—The Secretary,  
22 acting through the Director of BARDA,  
23 shall implement strategic initiatives, to be  
24 known as the Combating Antimicrobial Re-  
25 sistance Biopharmaceutical Accelerator

1 Program, including by building on existing  
2 programs and by awarding contracts,  
3 grants, and cooperative agreements, or en-  
4 tering into other transactions—

5 “(I) to optimize the use of  
6 antimicrobials in human and animal  
7 health settings;

8 “(II) to support innovative can-  
9 didate products in preclinical and clin-  
10 ical development that reduce anti-  
11 microbial resistance; and

12 “(III) to support research with  
13 respect to infection prevention and  
14 control to slow the spread of resistant  
15 bacteria, fungi, and viruses.

16 “(ii) REFERENCES.—Except as other-  
17 wise specified, any reference to the Com-  
18 bating Antibiotic Resistant Bacteria Bio-  
19 pharmaceutical Accelerator or the CARB-  
20 X program in any statute, Executive order,  
21 rule, regulation, directive, or other Federal  
22 document is deemed to be a reference to  
23 the Combating Antimicrobial Resistance  
24 Biopharmaceutical Accelerator Program  
25 under this subparagraph.

1                   “(iii) AUTHORIZATION OF APPROPRIA-  
2                   TIONS.—

3                   “(I) IN GENERAL.—To carry out  
4                   the program under clause (i), there is  
5                   authorized to be appropriated  
6                   \$500,000,000 for the period of fiscal  
7                   years 2022 through 2026, to remain  
8                   available until expended.

9                   “(II) REQUIREMENT.—Of the  
10                  amounts made available to carry out  
11                  the program under clause (i) for the  
12                  period of fiscal years 2022 through  
13                  2026, not less than 10 percent shall  
14                  be used to support antifungal product  
15                  development.”.

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