

118TH CONGRESS  
1ST SESSION

# H. R. 6731

To support endemic 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

DECEMBER 12, 2023

Mr. SCHWEIKERT (for himself, Mr. MCCARTHY, Mr. VALADAO, Mr. LAMALFA, Mr. STANTON, and Mr. CISCOMANI) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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.**

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 2023” or the “FOR-  
7 WARD Act of 2023”.

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

- Sec. 1. Short title.  
Sec. 2. Continuing support for research on endemic fungal diseases.  
Sec. 3. Endemic fungal disease working group.  
Sec. 4. Expanding tropical disease product priority review voucher program to encourage prevention and treatment of coccidioidomycosis.  
Sec. 5. 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 447D of such Act (42 U.S.C. 285f-5)  
5 the following new section:

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

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

9 “(1) continue to conduct or support basic,  
10 translational, and clinical research related to fungal  
11 diseases found in the United States, including coc-  
12 cidioidomycosis (commonly known as and referred to  
13 in this section as ‘Valley Fever’); and

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

18 “(b) REPORTS.—The Director of the Institute shall  
19 ensure that each triennial report under section 403 in-  
20 cludes information on actions undertaken by the National  
21 Institutes of Health to carry out subsection (a) with re-

1 spect to such fungal diseases, including coccidioidomy-  
2 cosis.

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-  
4 dition to other amounts available for the purposes of car-  
5 rying out this section, there is authorized to be appro-  
6 priated to carry out this section \$20,000,000 for each of  
7 fiscal years 2024 through 2028 for such purpose.”.

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

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

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

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

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

23 (b) DUTIES.—The Working Group shall—

24 (1) make recommendations to the Secretary, in-  
25 cluding an updated strategy related to development

1 of therapeutics and vaccines for endemic fungal dis-  
2 eases, that shall—

3 (A) take into account ongoing fungal dis-  
4 ease research, including for animals, that may  
5 be adapted for human use;

6 (B) identify gaps in endemic fungal disease  
7 research, including basic, clinical, and  
8 translational research related to the patho-  
9 genesis, prevention, diagnosis, and treatment of  
10 such diseases; and

11 (C) include recommendations for congres-  
12 sional action to spur additional research and  
13 product development for fungal diseases; and

14 (2) in implementing this subsection, solicit  
15 input from States, Tribes, localities, and nongovern-  
16 mental entities, including organizations representing  
17 patients, health care providers, researchers, and in-  
18 dustry regarding scientific advances, research ques-  
19 tions, and surveillance activities.

20 (c) MEMBERSHIP.—The members of the Working  
21 Group shall represent a diversity of scientific disciplines  
22 and shall be composed of the following members:

23 (1) FEDERAL MEMBERS.—Seven Federal mem-  
24 bers, consisting of one or more representatives of  
25 each of the following:

1 (A) The Office of the Assistant Secretary  
2 for Health, who shall serve as Chair.

3 (B) The Food and Drug Administration.

4 (C) The Centers for Disease Control and  
5 Prevention.

6 (D) The National Institutes of Health, who  
7 shall serve as Vice Chair.

8 (E) Such other agencies and offices of the  
9 Department of Health and Human Services as  
10 the Secretary determines appropriate.

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

14 (A) Physicians, veterinarians, and other  
15 medical providers with experience in diagnosing  
16 and treating endemic fungal disease.

17 (B) Scientists or researchers with expertise  
18 in endemic fungal disease.

19 (C) Patients who have been diagnosed with  
20 an endemic fungal disease and family members  
21 or caregivers of such patients, as applicable.

22 (D) Nonprofit organizations that advocate  
23 for patients with respect to endemic fungal dis-  
24 ease.

1           (E) Other individuals whose expertise is  
2           determined by the Secretary to be beneficial to  
3           the functioning of the Working Group.

4           (d) MEETINGS.—The Working Group shall meet not  
5           less frequently than annually.

6           (e) REPORTING.—Not later than 1 year after the  
7           date of enactment of this Act, and annually thereafter  
8           until termination of the Working Group pursuant to sub-  
9           section (g), the Secretary shall—

10           (1) submit a report on recommendations re-  
11           ceived under subsection (b)(1) to the Committee on  
12           Health, Education, Labor, and Pensions of the Sen-  
13           ate and the Committee on Energy and Commerce of  
14           the House of Representatives; and

15           (2) make such report publicly available on the  
16           website of the Department of Health and Human  
17           Services.

18           (f) APPLICABILITY OF FACCA.—The Working Group  
19           shall be treated as an advisory committee subject to chap-  
20           ter 10 of part I of title 5, United States Code (commonly  
21           referred to as the “Federal Advisory Committee Act”).

22           (g) SUNSET.—The Working Group under this section  
23           shall terminate 5 years after the date of enactment of this  
24           Act.

1 (h) ENDEMIC FUNGAL DISEASE DEFINED.—In this  
2 section, the term “endemic fungal disease” means blasto-  
3 mycosis, coccidioidomycosis, histoplasmosis, and  
4 sparotrichosis.

5 **SEC. 4. EXPANDING TROPICAL DISEASE PRODUCT PRI-**  
6 **ORITY REVIEW VOUCHER PROGRAM TO EN-**  
7 **COURAGE PREVENTION AND TREATMENT OF**  
8 **COCCIDIOIDOMYCOSIS.**

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

11 (1) by redesignating subparagraph (S) as sub-  
12 paragraph (T); and

13 (2) by inserting after subparagraph (R) the fol-  
14 lowing:

15 “(S) Coccidioidomycosis.”.

16 **SEC. 5. COMBATING ANTIMICROBIAL RESISTANCE BIO-**  
17 **PHARMACEUTICAL ACCELERATOR PROGRAM.**

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

21 “(H) COMBATING ANTIMICROBIAL RESIST-  
22 ANCE BIOPHARMACEUTICAL ACCELERATOR PRO-  
23 GRAM.—

24 “(i) IN GENERAL.—The Secretary,  
25 acting through the Director of BARDA,

1 shall implement strategic initiatives, to be  
2 known as the Combating Antimicrobial Re-  
3 sistance Biopharmaceutical Accelerator  
4 Program, including by building on existing  
5 programs and by awarding contracts,  
6 grants, and cooperative agreements, or en-  
7 tering into other transactions—

8 “(I) to optimize the use of  
9 antimicrobials in human health set-  
10 tings;

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

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

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

1 the Combating Antimicrobial Resistance  
2 Biopharmaceutical Accelerator Program  
3 under this subparagraph.

4 “(iii) AUTHORIZATION OF APPROPRIA-  
5 TIONS.—

6 “(I) IN GENERAL.—To carry out  
7 the program under clause (i), there is  
8 authorized to be appropriated  
9 \$500,000,000 for the period of fiscal  
10 years 2024 through 2028, to remain  
11 available until expended.

12 “(II) REQUIREMENT.—Of the  
13 amounts made available to carry out  
14 the program under clause (i) for the  
15 period of fiscal years 2024 through  
16 2028, not less than 20 percent shall  
17 be used to support antifungal product  
18 development.”.

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