

118TH CONGRESS
1ST SESSION

S. 3464

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

DECEMBER 12, 2023

Mr. KELLY (for himself and Ms. SINEMA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 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; table of contents.
 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 the
20 Federal Advisory Committee Act (5 U.S.C. App.).

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

24 (h) ENDEMIC FUNGAL DISEASE DEFINED.—In this
25 section, the term “endemic fungal disease” means blasto-

1 mycosis, coccidioidomycosis, histoplasmosis, and
2 sparotrichosis.

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

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) Coccidioidomycosis.”.

14 **SEC. 5. COMBATING ANTIMICROBIAL RESISTANCE BIO-**
15 **PHARMACEUTICAL ACCELERATOR PROGRAM.**

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

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

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

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

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

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

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

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

1 Biopharmaceutical Accelerator Program
2 under this subparagraph.

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

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

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

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