117TH CONGRESS
2D SESSION

S. 3498

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

JANUARY 13 (legislative day, JANUARY 10), 2022

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

(a) IN GENERAL.—This Act may be cited as the ''Finding Orphan-disease Remedies With Antifungal Research and Development Act of 2022'' or the ''FORWARD Act of 2022''.

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

SEC. 2. CONTINUING SUPPORT FOR RESEARCH ON ENDEMIC FUNGAL DISEASES.

The Public Health Service Act is amended by inserting after section 447C of such Act (42 U.S.C. 285f–4) the following new section:

"SEC. 447D. ENDEMIC FUNGAL DISEASES.

''(a) IN GENERAL.—The Director of the Institute shall—

''(1) 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'); and

''(2) subject to the availability of appropriations, make grants to, or enter into contracts with, public or nonprofit private entities to conduct such research.

''(b) REPORTS.—The Director of the Institute 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) AUTHORIZATION OF APPROPRIATIONS.—In addition to other amounts available for the purposes of carrying out this section, there is authorized to be appropriated to carry out this section $20,000,000 for each of fiscal years 2022 through 2026 for such purpose.''.

SEC. 3. ENDEMIC FUNGAL DISEASE WORKING GROUP.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a working group, to be known as the Endemic Fungal Disease Working Group (referred to in this section as the ''Working Group''), comprised of representatives of appropriate Federal agencies and other non-Federal entities—

(1) to provide expertise and to review all efforts within the Department of Health and Human Services related to endemic fungal disease;

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

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

(b) RESPONSIBILITIES.—The Working Group shall—

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

(A) ongoing endemic fungal disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with an endemic fungal disease;

(B) advances made pursuant to such research;

(C) the impact of viral respiratory illnesses, including COVID–19, and fungal lung diseases and pneumonias;

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

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

(ii) basic, clinical, and translational endemic fungal disease research related to the pathogenesis, prevention, diagnosis, and treatment of endemic fungal disease;

(E) gaps in endemic fungal disease research described in subparagraph (D)(ii);

(F) the Working Group's meetings required under subsection (d); and

(G) the comments received by the Working Group;

(2) make recommendations to the Secretary, including a proposed strategy related to development of therapeutics and vaccines, regarding any appropriate changes or improvements to such activities described in paragraph (1); and

(3) in implementing this subsection, solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, and surveillance activities.

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

(1) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of the following:

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

(B) The Food and Drug Administration.

(C) The Centers for Disease Control and Prevention.

(D) The National Institutes of Health.

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

(2) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

(A) Physicians and other medical providers with experience in diagnosing and treating endemic fungal disease.

(B) Scientists or researchers with expertise.

(C) Patients and their family members.

(D) Nonprofit organizations that advocate for patients with respect to endemic fungal disease.

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

(d) MEETINGS.—The Working Group shall meet annually.

(e) REPORTING.—Not later than 2 years after the date of enactment of this Act, and every 2 years thereafter until termination of the Working Group pursuant to subsection (g), the Working Group shall—

(1) submit a report on its activities under subsection (b)(1) and any recommendations under paragraph (b)(2) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

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

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

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

(h) ENDEMIC FUNGAL DISEASE DEFINED.—In this section, the term ''endemic fungal disease'' means blastomycosis, coccidioidomycosis, histoplasmosis, and sparotrichosis.

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

(a) DRAFT GUIDANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of

Food and Drugs, shall issue draft guidance for industry for the purposes of assisting entities seeking approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of antifungal therapies, diagnostics, or vaccines, specifically therapies, diagnostics, and vaccines designed to diagnose, treat, or prevent coccidioidomycosis (commonly known as Valley Fever).

(b) FINAL GUIDANCE.—Not later than 18 months after the close of the public comment period on the draft guidance issued pursuant to subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance.

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

SEC. 5. PRIORITY REVIEW; FAST TRACK PRODUCT.

(a) PRIORITY REVIEW.—

(1) IN GENERAL.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by striking ''then the Secretary shall give priority review to the first applica-

tion submitted for approval for such drug under section 505(b)'' and inserting ''or if the drug is a biological product intended to treat coccidioidomycosis, then the Secretary shall give priority review to the first application submitted for approval for such drug under section 505(b) of this Act or section 351(a) of the Public Health Service Act''.

(2) APPLICABILITY.—The amendment made by paragraph (1) applies only to any application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of enactment of this Act.

(b) FAST TRACK PRODUCT.—Section 506(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(b)(1)) is amended by striking ''or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' and inserting '', if the Secretary designates the drug as a qualified infectious disease product under section 505E(d), or if the drug is a biological product intended to treat coccidioidomycosis''.

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

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

(1) by redesignating subparagraph (S) as subparagraph (T); and

(2) by inserting after subparagraph (R) the following:

''(S) Coccidioidomycosis.''.

SEC. 7. COMBATING ANTIMICROBIAL RESISTANCE BIOPHARMACEUTICAL ACCELERATOR PROGRAM.

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

''(G) COMBATING ANTIMICROBIAL RESISTANCE BIOPHARMACEUTICAL ACCELERATOR PROGRAM.—

''(i) IN GENERAL.—The Secretary, acting through the Director of BARDA, shall implement strategic initiatives, to be known as the Combating Antimicrobial Resistance Biopharmaceutical Accelerator Program, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions—

''(I) to optimize the use of antimicrobials in human and animal health settings;

''(II) to support innovative candidate products in preclinical and clinical development that reduce antimicrobial resistance; and

''(III) to support research with respect to infection prevention and control to slow the spread of resistant bacteria, fungi, and viruses.

''(ii) REFERENCES.—Except as otherwise specified, any reference to the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator or the CARB-X program in any statute, Executive order, rule, regulation, directive, or other Federal document is deemed to be a reference to the Combating Antimicrobial Resistance Biopharmaceutical Accelerator Program under this subparagraph.

''(iii) AUTHORIZATION OF APPROPRIATIONS.—

''(I) IN GENERAL.—To carry out the program under clause (i), there is authorized to be appropriated $500,000,000 for the period of fiscal

years 2022 through 2026, to remain available until expended.

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

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