117TH CONGRESS
1ST SESSION

S. 1548

To amend the Public Health Service Act to improve the diversity of participants in research on Alzheimer's disease, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 11, 2021

Mr. LUJÁN (for himself and Ms. COLLINS) 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 amend the Public Health Service Act to improve the diversity of participants in research on Alzheimer's disease, 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.

This Act may be cited as the ''Equity in Neuroscience and Alzheimer's Clinical Trials Act of 2021'' or the ''ENACT Act of 2021''.

SEC. 2. INCENTIVES, IMPROVEMENTS, AND OUTREACH TO INCREASE DIVERSITY IN ALZHEIMER'S DISEASE RESEARCH.

(a) IMPROVING ACCESS FOR AND OUTREACH TO UNDERREPRESENTED POPULATIONS.—

(1) EXPANDING ACCESS TO ALZHEIMER'S RESEARCH CENTERS.—

(A) IN GENERAL.—Section 445(a)(1) of the Public Health Service Act (42 U.S.C. 285e–2(a)(1)) is amended—

(i) by striking ''(a)(1) The Director of the Institute may'' and inserting the following:

''(a)(1) The Director of the Institute—

''(A) may'';

(ii) by striking ''disease.'' and inserting ''disease; and''; and

(iii) by adding at the end the following:

''(B) beginning January 1, 2022, shall enter into cooperative agreements and make grants to public or private nonprofit entities under this subsection for the planning, establishment, and operation of new such centers that are located in areas with a higher concentration of minority groups (as determined under section 444(d)(3)(D)), such as en-

tities that are historically Black colleges and universities, Hispanic-serving institutions, Tribal colleges and universities, or centers of excellence for other minority populations.''.

(B) USE OF FUNDING FOR CLINICS TO OPERATE CLINICAL TRIALS.—Section 445(b) of the Public Health Service Act (42 U.S.C. 285e–2(b)) is amended by adding at the end the following:

''(3) Federal payments made under a cooperative agreement or grant under subsection (a) from funds made available under section 2(g) of the ENACT Act of 2021 shall, with respect to Alzheimer's disease, be used in part to establish and operate diagnostic and treatment clinics designed—

''(A) to meet the special needs of minority and rural populations and other underserved populations; and

''(B) to operate clinical trials''.

(2) OUTREACH.—

(A) ALZHEIMER'S DISEASE CENTERS.—Section 445(b) of the Public Health Service Act (42 U.S.C. 285e–2(b)), as amended by paragraph (1)(B), is further amended by adding at the end the following new paragraph:

''(4) Federal payments made under a cooperative agreement or grant under subsection (a) shall be used to establish engagement centers to carry out public outreach, education efforts, and dissemination of information for members of minority groups about clinical trial participation. Activities funded pursuant to the preceding sentence shall include—

''(A) using established mechanisms to encourage members of minority groups to participate in clinical trials on Alzheimer's disease;

''(B) expanding education efforts to make members of minority groups aware of ongoing clinical trials;

''(C) working with trial sponsors to increase the number of recruitment events for members of minority groups;

''(D) conducting outreach to national, State, and local physician professional organizations, especially for members of such organizations who are primary care physicians or physicians who specialize in dementia, to increase awareness of clinical research opportunities for members of minority groups; and

''(E) using community-based participatory research methodologies to engage with minority populations.''.

(B) RESOURCE CENTERS FOR MINORITY AGING RESEARCH.—Section 444(c) of the Public Health Service Act (42 U.S.C. 285e–1(c)) is amended—

(i) by striking ''(c)'' and inserting ''(c)(1)'' ; and

(ii) by adding at the end the following new paragraph:

''(2) The Director, acting through the Resource Centers for Minority Aging Research of the Institute, shall carry out public outreach, education efforts, and dissemination of information for members of minority groups about participation in clinical research on Alzheimer's disease carried out or supported under this subpart.''.

(b) INCENTIVES TO INCREASE DIVERSITY IN ALZHEIMER'S DISEASE RESEARCH THROUGH PRINCIPAL INVESTIGATORS AND RESEARCHERS FROM UNDERREPRESENTED POPULATIONS.—

(1) ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.—Section 445I of the Public Health Service Act (42 U.S.C. 285e–10a) is amend-

ed by adding at the end the following new subsection:

''(d) ENHANCING THE PARTICIPATION OF PRINCIPAL INVESTIGATORS AND RESEARCHERS WHO ARE MEMBERS OF UNDERREPRESENTED POPULATIONS.—

''(1) IN GENERAL.—The Director shall enhance diversity in the conduct or support of clinical research on Alzheimer's disease under this subpart by encouraging the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences as principal investigators of such clinical research, as researchers for such clinical research, or both.

''(2) TRAINING FOR PRINCIPAL INVESTIGATORS.—The Director of the Institute shall provide training for principal investigators who are members of a minority group with respect to skills for—

''(A) the design and conduct of clinical research and clinical protocols;

''(B) applying for grants for clinical research; and

''(C) such other areas as the Director determines to be appropriate.''.

(2) SENIOR RESEARCHER AWARDS.—Section 445B(a) of the Public Health Service Act (42

U.S.C. 285e–4(a)) is amended by inserting ", including senior researchers who are members of a minority group" before the period at the end of the first sentence.

(c) INCENTIVES TO INCREASE DIVERSITY IN ALZHEIMER'S DISEASE RESEARCH THROUGH TRIAL SITES.—Section 444(d) of the Public Health Service Act (42 U.S.C. 285e–1(d)) is amended—

(1) by striking "(d)" and inserting "(d)(1)" ; and

(2) by adding at the end the following new paragraphs:

"(2) In conducting or supporting clinical research on Alzheimer's disease for purposes of this subpart, in addition to requirements otherwise imposed under this title, including under section 492B, the Director of the Institute shall increase the participation of members of minority groups in such clinical research through one or more of the activities described in paragraph (3).

"(3)(A) The Director of the Institute shall provide incentives for the support of clinical research on Alzheimer's disease with clinical trial sites established in areas with a higher concentration of minority groups, including rural areas if practicable.

''(B) In determining whether to conduct or support clinical research on Alzheimer's disease, the Director of the Institute shall encourage the conduct of clinical research with clinical trial sites in areas described in subparagraph (A) as a higher-level priority criterion among the criteria established to evaluate whether to conduct or support clinical research.

''(C) In determining the amount of funding to be provided for the conduct or support of such clinical research, the Director of the Institute shall provide additional funding for the conduct of such clinical research with clinical trial sites in areas described in subparagraph (A).

''(D) In determining whether an area is an area with a higher concentration of minority groups, the Director of the Institute—

''(i) shall consider the most recent data collected by the Bureau of the Census; and

''(ii) may also consider—

''(I) data from the Centers for Medicare & Medicaid Services on the incidence of Alzheimer's disease in the United States by region; and

''(II) such other data as the Director determines appropriate.

''(4) In order to facilitate the participation of members of minority groups in clinical research supported under this subpart, in addition to activities described in paragraph (3), the Director of the Institute shall—

''(A) ensure that such clinical research uses community-based participatory research methodologies; and

''(B) encourage the use of remote health technologies, including telehealth, remote patient monitoring, and mobile technologies, that reduce or eliminate barriers to participation of members of minority groups in such clinical research.

''(5)(A) Clinical research on Alzheimer's disease conducted or supported under this subpart shall ensure that such research includes outreach activities designed to increase the participation of members of minority groups in such research.

''(B)(i) Each applicant for a grant under this subpart for clinical research on Alzheimer's disease shall submit to the Director of the Institute in the application for such grant—

''(I) a budget for outreach activities to members of minority populations with respect to participation in such clinical research; and

''(II) a description of the plan to conduct such outreach.

''(ii) The Director of the Institute shall encourage applicants for, and recipients of, grants under this subpart to conduct clinical research on Alzheimer's disease to engage with community-based organizations to increase participation of minority populations in such research.

''(6) For purposes of this subpart:

''(A) The term 'clinical research' includes a clinical trial.

''(B) The term 'minority group' has the meaning given such term by reason of section 492B(g).''.

(d) PARTICIPANT ELIGIBILITY CRITERIA.—Section 445I of the Public Health Service Act (42 U.S.C. 285e–10a), as amended by subsection (b)(1), is further amended by adding at the end the following new subsection:

''(e) PARTICIPANT ELIGIBILITY CRITERIA.—The Director of the Institute shall take such actions as are necessary to ensure that clinical research on Alzheimer's disease conducted or supported under this subpart is designed with eligibility criteria that ensure the clinical trial population reflects the diversity of the prospective patient population. Such actions may include the following:

''(1) EXAMINATION OF CRITERIA.—

"(A) IN GENERAL.—An examination of each exclusion criterion to determine if the criterion is necessary to ensure the safety of trial participants or to achieve the study objectives.

"(B) MODIFICATION OF CRITERIA.—In the case of an exclusion criterion that is not necessary to ensure the safety of trial participants or to achieve the study objectives—

"(i) encouraging the modification or elimination of the criterion; or

"(ii) encouraging tailoring the criterion as narrowly as possible to avoid unnecessary limits to the population of the clinical study.

"(2) REQUIREMENT FOR STRONG JUSTIFICATION FOR EXCLUSION.—A review of each exclusion criterion to ensure that populations are included in clinical trials, such as older adults, individuals with a mild form of disease, individuals at the extremes of the weight range, or children, unless there is a strong clinical or scientific justification to exclude them.

"(3) USE OF ADAPTIVE DESIGN.—Encouraging the use of an adaptive clinical trial design that—

''(A) starts with a defined population where there are concerns about safety; and

''(B) may expand to a broader population based on initial data from the trial and external data.''.

(e) RESOURCE CENTER FOR SUCCESSFUL STRATEGIES TO INCREASE PARTICIPATION OF UNDERREPRESENTED POPULATIONS IN ALZHEIMER'S DISEASE CLINICAL RESEARCH.—Section 444 of the Public Health Service Act (42 U.S.C. 285e–1) is amended by adding at the end the following new subsection:

''(e)(1) Acting through the Office of Special Populations of the Institute and in consultation with the Division of Extramural Activities, the Director of the Institute shall support resource information and technical assistance to grantees under section 445 (relating to Alzheimer's disease centers), other grantees, and prospective grantees, designed to increase the participation of minority populations in clinical research on Alzheimer's disease conducted or supported under this subpart.

''(2) The resource information and technical assistance provided under paragraph (1) shall include the maintenance of a central resource library in order to collect, prepare, analyze, and disseminate information relating to strategies and best practices used by recipients of grants

under this subpart and other researchers in the development of the clinical research designed to increase the participation of minority populations in such clinical research.''.

(f) ANNUAL REPORTS.—Section 444 of the Public Health Service Act (42 U.S.C. 285e–1), as amended by subsection (e), is further amended by adding at the end the following new subsection:

''(f)(1)(A) The Director of the Institute shall submit annual reports to Congress on the impact of the amendments made to this subpart by the ENACT Act of 2021.

''(B) The Secretary shall transmit a copy of each such report to the Advisory Council on Alzheimer's Research, Care, and Services established under section 2(e) of the National Alzheimer's Project Act (Public Law 111–375).

''(2) In each report under paragraph (1), the Director of the Institute shall include information and data on the following matters with respect to clinical trials on Alzheimer's disease conducted during the preceding year:

''(A) The number of participants who are members of a minority group in such clinical trials.

''(B) The number of such clinical trials for which incentives under subsection (d)(3) were made available, the nature of such incentives, the amount

of increased funding (if any) made available for research on Alzheimer's disease, and the training provided to principal investigators who are members of a minority group and the amount of funding (if any) for such training.

''(C) The number of such clinical trials for which the principal investigator is a member of a minority group.

''(D) The number of such clinical trials for which a significant percentage of researchers are members of a minority group.

''(E) Modifications to patient eligibility criteria in clinical trial designs under section 445I(e).

''(F) Outreach and education efforts conducted under section 445(b)(3).

''(3) The Director of the Institute shall make each report under paragraph (1) available to the public, including through posting on the appropriate website of the Department of Health and Human Services.''.

(g) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2022 through 2026, there is authorized to be appropriated to the Secretary of Health and Human Services $60,000,000 to carry out the amendments made by this section, to remain available until expended.

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