I

118TH CONGRESS
1ST SESSION

H. R. 3503

To direct the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to take certain steps to increase clinical trial diversity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 2023

Ms. KELLY of Illinois (for herself and Mr. FITZPATRICK) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To direct the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to take certain steps to increase clinical trial diversity, 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 ''NIH Clinical Trial Diversity Act of 2023''.

SEC. 2. DIVERSITY GOALS FOR CLINICAL TRIALS.

(a) APPLICATIONS.—Beginning on the date of the enactment of this Act, the Secretary of Health and Human

Services, acting through the Director of the National Institutes of Health (in this section referred to as the ''Secretary''), shall require that a sponsor seeking to conduct a clinical trial investigating a drug, device (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.)) biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))), or behavioral intervention, the protocol for which is approved by the National Institutes of Health, to submit an application (or renewal thereof) for such approval that includes—

(1) clear and measurable goals for the recruitment and retention of participants that reflect—

(A) the race, ethnicity, age, and sex of patients with the disease or condition being investigated; or

(B) the race, ethnicity, age, and sex of the general population of the United States if the prevalence of the disease or condition is not known;

(2) a rationale for the goals specified under paragraph (1) that specifies—

(A) how investigators will calculate the number of participants for each population cat-

egory that reflect the population groups specified in paragraph (1); or

(B) strategies that will be used to enroll and retain participants across the different race, ethnicity, age, and sex categories;

(3) a detailed plan for how the clinical trial will achieve the goals specified under paragraph (1) that specifies—

(A) the requirements for researchers, in conducting the trial, to analyze the population groups specified in paragraph (1) separately;

(B) the role of community partners or community institutional review boards in reviewing the plans; and

(C) how the trial will recruit a study population that is—

(i) in proportion to the prevalence of the disease or condition in such groups relative to the prevalence of the disease or condition in the overall population of the United States;

(ii) in sufficient numbers to obtain clinically and statistically meaningful determinations of the safety and effectiveness of the drug, device, biological product, or

behavioral intervention being studied in the respective race, ethnicity, age, and sex groups; and

(iii) consistent with the guidance under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) and guidance issued by the National Institutes of Health on the inclusion of women and minorities in clinical trials;

(4) the sponsor's plan for implementing, or an explanation of why the sponsor cannot implement, alternative clinical trial follow-up requirements that are less burdensome for trial participants, such as—

(A) requiring fewer follow-up visits;

(B) allowing phone follow-up or home visits by nurse trial coordinators (in lieu of in-person visits by patients);

(C) allowing for online follow-up options;

(D) permitting the patient's primary care provider to perform some of the follow-up visit requirements;

(E) allowing for evening and weekend hours for required follow-up visits;

(F) allowing virtual or telemedicine visits;

(G) use of wearable technology to record key health parameters; and

(H) use of alternate labs or imaging centers, which may be closer to the residence of the patients participating in the trial; and

(5) the sponsor's education and training requirements for researchers and other individuals conducting or supporting the clinical trial with respect to diversity and health inequities in, and the development of, curricula for healthcare professionals on how to participate in clinical trials as an investigator and how they can enroll patients in trials, which may include consultation with, and the review of materials made available by, such committees, task forces, working groups, and other entities the Director determines are appropriate, including the following:

(A) The Equity Committee of the National Institutes of Health.

(B) The National Advisory Council on Minority Health and Health Disparities.

(C) The Advisory Committee on Research on Women's Health.

(D) The Tribal Health Research Coordinating Committee of the National Institutes of Health.

(b) TERMS.—

(1) IN GENERAL.—As a condition on the approval of a protocol to conduct a clinical trial by the National Institutes of Health, as described in subsection (a), the sponsor of the clinical trial shall agree to terms requiring that—

(A) the aggregate demographic information of trial participants be shared on an annual basis with the Secretary while participant recruitment and data collection in such trial is ongoing, and that such information is provided with respect to—

(i) underrepresented populations, including populations grouped by race, ethnicity, age, and sex; and

(ii) such populations that reflect the prevalence of the disease or condition that is the subject of the clinical trial involved (as available and as appropriate to the scientific objective for the study, as determined by the Director of the National Institutes of Health);

(B) the sponsor submits to the program officer and grants management specialist of the specific National Institutes of Health national research institute or national center, annually or as frequently as such officer or specialist determines necessary, the retention rate of participants in the clinical trial, disaggregated by race, ethnicity, age, and sex;

(C) both the clinical trial researchers and the applicant reviewers complete education and training programs on diversity in clinical trials; and

(D) at the conclusion of the trial, the sponsor submits to the Secretary the number of participants in the trial, disaggregated by race, ethnicity, age, and sex.

(2) PRIVACY PROTECTIONS.—Any data shared under paragraph (1) may not include any individually identifiable information or protected health information with respect to clinical trial participants and shall only be disclosed to the extent allowed under Federal privacy laws.

(c) EXCEPTION.—In lieu of submitting an application under subsection (a) and documentation of goals as required by paragraph (1) of such subsection, an applicant

may provide reasoning for why the recruitment of each of the population groups specified in paragraph (1) of subsection (a) is not necessary and why such recruitment is not scientifically justified or possible.

(d) PUBLICATION.—The Secretary shall—

(1) publish on a public website of the National Institutes of Health, upon receipt of an application to which subsection (a) applies—

(A) a summary of the disease being targeted in the clinical trial that is the subject of the application and the prevalence of such disease across race, ethnicity, age, sex, and the clinical trial representation in each such category;

(B) the goals specified in such application, as required by subsection (a)(1); or

(C) the reasoning described in subsection (c); and

(2) ensure that, in publishing information relating to an application under paragraph (1), the design of the study involved is not disclosed.

(e) REMEDIATION.—

(1) IN GENERAL.—In the case of a clinical trial subject to subsection (a) that fails to meet the condition specified pursuant to subsection (a) by such

date as may be agreed upon by the sponsor of the trial and the program officer and grants management specialist of the specific National Institutes of Health national research institute or national center, the Secretary shall require the sponsor of that clinical trial, not later than 90 days after such date occurs—

(A) to develop, in consultation with the Secretary and advocacy and community-based organizations representing individuals who are members of relevant demographic groups specified in subsection (a)(1), a strategic plan to increase participation in such clinical trial of such individuals; and

(B) to submit to the Secretary such strategic plan.

(2) PUBLICATION.—The Secretary shall make publicly available on the website of the National Institutes of Health, the strategic plan received under paragraph (1) as soon as possible after receipt. The Secretary shall ensure that, in publishing such plan under the preceding sentence, the design of the study involved is not disclosed.

(3) IMPLEMENTATION.—The sponsor of the clinical trial that is the subject of the strategic plan

published under paragraph (2), shall, not later than 90 days after such date as may be agreed upon by the sponsor of the trial and the appropriate program officer and grants management specialist of the National Institutes of Health, implement the strategic plan.

(4) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to a sponsor of a clinical trial, as necessary for the sponsor to meet the requirements of paragraph (3).

(f) WAIVER FOR CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—In the case of a clinical trial that received funding through the National Institutes of Health and is ongoing as of the date of the enactment of this Act, the sponsor of such clinical trial is exempt from the requirements of (and associated penalties imposed by) this Act.

(2) REPORT.—The Secretary shall include in the triennial report required to be submitted under section 403 of the Public Health Service Act (42 U.S.C. 283), a list of all clinical trials receiving funding through the National Institutes of Health that requested and received waivers under this section.

(g) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study that—

(A) examines which actions Federal agencies have taken to address barriers to participation in federally funded clinical trials by the demographic groups specified in subsection (a)(1); and

(B) identifies challenges, if any, in implementing such actions.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the findings of the study conducted under paragraph (1).

(h) NONDISCRIMINATION.—Section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116) shall apply with respect to a clinical trial subject to subsection (a).

SEC. 3. ELIMINATING COST BARRIERS.

Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health (referred to in this section as the ''Secretary''), shall conduct and complete a study on—

(1) the need for review of human subject regulations specified in part 46 of title 45, Code of Federal Regulations (or successor regulations), and related guidance;

(2) the modernization of such regulations and guidance to establish updated guidelines for reimbursement of out-of-pocket expenses of human subjects, compensation of human subjects for time spent participating in the clinical trial, and incentives for recruitment of human subjects; and

(3) the need for updated safe harbor rules under section 1001.952 of title 42, Code of Federal Regulations (or successor regulations) and section 1128B of the Social Security Act (commonly referred to as the Federal Anti-Kickback Statute (42 U.S.C. 1320a–7b)) with respect to the assistance provided under this section.

SEC. 4. PUBLIC AWARENESS AND EDUCATION CAMPAIGN.

(a) NATIONAL CAMPAIGN.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health and the Commissioner of Food and Drugs (referred to in this section as the ''Secretary'') and in consultation with the stakeholders specified in subsection (e), shall carry out a national campaign to increase the awareness and knowledge of individuals in

the United States, including healthcare professionals, patients, and others, with respect to the need for diverse clinical trials among the demographic groups identified pursuant to section 2(a)(1).

(b) REQUIREMENTS.—The national campaign conducted under this section shall include—

(1)(A) the development and distribution of written educational materials;

(B) the development and placing of public service announcements that are intended to encourage individuals who are members of the demographic groups identified pursuant to section 2(b)(1)(A)(I) to seek to participate in clinical trials; and

(C) the development of curricula for health care professionals on—

(i) how to participate in clinical trials as an investigator; and

(ii) how such professionals can enroll patients in trials;

(2) such efforts as are reasonable and necessary to ensure meaningful access by consumers with limited English proficiency;

(3) the development and distribution of best practices and training for recruiting underrepresented study populations, including a method for

sharing such best practices among clinical trial sponsors, providers, community-based organizations who assist with recruitment, and with the public; and

(4) the conduct of focus groups to better understand the concerns and fears of certain underrepresented groups who may be reluctant to participate in clinical trials.

(c) HEALTH INEQUITIES.—In developing the national campaign under subsection (a), the Secretary shall recognize and address—

(1) health inequities among individuals who are members of the population groups specified in section 2(b)(1)(A) with respect to access to care and participation in clinical trials; and

(2) any barriers in access to care and participation in clinical trials that are specific to individuals who are members of such groups.

(d) GRANTS.—The Secretary shall establish a program to award grants to nonprofit private entities (including community based organizations and faith communities, institutions of higher education eligible to receive funds under section 371 of the Higher Education Act of 1965 (20 U.S.C. 1067q), national organizations that serve underrepresented populations, and community pharmacies) to enable such entities—

(1) to test alternative outreach and education strategies to increase the awareness and knowledge of individuals in the United States, with respect to the need for diverse clinical trials that reflect the race, ethnicity, age, and sex of patients with the disease or condition being investigated; and

(2) to cover administrative costs of such entities in assisting in diversifying clinical trials subject to section 2.

(e) STAKEHOLDERS SPECIFIED.—The stakeholders specified in this subsection are the following:

(1) Representatives of the Health Resources Services Administration, the Office on Minority Health of the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health.

(2) Community-based resources and advocates.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2025 through 2028.

SEC. 5. DEFINITIONS.

In this Act:

(1) CLINICAL TRIAL.—The term ''clinical trial'' means a research study in which one or more human subjects are prospectively assigned to one or more

interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

(2) SPONSOR.—The term ''sponsor'' has the meaning given such term in section 50.3 of title 21, Code of Federal Regulations (or successor regulations).

○