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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To direct the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. ESHOO introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Commissioner of Food and Drugs to amend certain regulations 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 ''Diverse and Equitable Participation in Clinical Trials Act'' or the ''DEPICT Act''.

SEC. 2. PREMARKET REPORTING OF DIVERSITY PLANS FOR CLINICAL TRIALS AND STUDIES.

(a) DRUGS.—The Commissioner of Food and Drugs shall issue regulations revising part 312 of title 21, Code, of Federal Regulations, to require sponsors of applications for an exemption for investigational use of a drug to include—

(1) in any such application—

(A) the estimated prevalence in the United States of the disease or condition for which the drug is being developed or investigated, disaggregated by demographic subgroup, where such data is available, including age group, sex, race, and ethnicity;

(B) the sponsor's targets for enrollment in the clinical trial or trials involved, disaggregated by age group, sex, race, and ethnicity;

(C) the rationale for the sponsor's enrollment targets referred to in subparagraph (B), which may include—

(i) the estimated prevalence referred to in subparagraph (A);

(ii) what is known about the disease or condition for which the drug is being developed or investigated;

(iii) any relevant pharmacokinetic or pharmacogenomic data;

(iv) what is known about the patient population, including co-morbidities and potential barriers to enrolling diverse participants, such as patient population size and geographic location; and

(v) any other data or information the sponsors deems relevant to selecting appropriate enrollment targets, disaggregated by demographic subgroup; and

(D) a diversity action plan for how the sponsor will meet such targets, including demographic-specific outreach and enrollment strategies, study-site selection, clinical trial inclusion and exclusion practices, and any diversity training for trial personnel; and

(2) in an annual report described in section 312.33 of title 21, Code of Federal Regulations—

(A) the sponsor's progress in meeting the targets referred to in paragraph (1)(B); and

(B) if the sponsor does not expect to meet those targets referred to in paragraph (1)(B)—

(i) any updates needed to be made to the diversity action plan referred to in paragraph (1)(D) to meet such targets; or

(ii) the sponsor's justification for why the sponsor does not expect to meet such targets, including—

(I) any factors outside of the sponsor's control, including a lack of retention of participants;

(II) any differences in the enrollment targets, disaggregated by demographic subgroup, and actual enrollment that the sponsor determines are insignificant in nature ;

(III) potential for selection bias;

(IV) information not available to the sponsor at the time such targets were chosen, but that impacted enrollment of diverse participants.

(b) DEVICES.—The Commissioner of Food and Drugs shall issue regulations revising part 812 of title 21, Code, of Federal Regulations, to require sponsors of applications for an exemption for investigational use of a device to include—

(1) in any such application—

(A) a description of the patient population in the United States expected to use the device, disaggregated by demographic subgroup, where such data is available, including age group, sex, race, and ethnicity;

(B) the sponsor's targets for enrollment in the clinical trial or trials involved, disaggregated by age group, sex, race, and ethnicity;

(C) the rationale for the sponsor's enrollment targets referred to in subparagraph (B), which may include—

(i) the estimated prevalence referred to in subparagraph (A);

(ii) what is known about the disease or condition for which the drug is being developed or investigated;

(iii) any relevant pharmacokinetic or pharmacogenomic data;

(iv) what is known about the patient population, including co-morbidities and potential barriers to enrolling diverse participants, such as patient population size and geographic location; and

(v) any other data or information the sponsors deems relevant to selecting appropriate enrollment targets, disaggregated by demographic subgroup; and

(D) a diversity action plan for how the sponsor will meet such targets, including demographic-specific outreach and enrollment strategies, study-site selection, clinical trial inclusion and exclusion practices, and any diversity training for trial personnel; and

(2) in an annual report described in section 812.150 of title 21, Code of Federal Regulations—

(A) the sponsor's progress in meeting those targets referred to in paragraph (1)(B); and

(B) if the sponsor does not expect to meet those targets referred to in paragraph (1)(B)—

(i) any updates needed to be made to the diversity action plan referred to in paragraph (1)(D) to meet such targets; or

(ii) the sponsor's justification for why the sponsor does not expect to meet such targets, including—

(I) any factors outside of the sponsor's control, including a lack of retention of participants;

(II) any differences in the enrollment targets, disaggregated by demographic subgroup, and actual enrollment that the sponsor determines are insignificant in nature ;

(III) potential for selection bias; and

(IV) information not available to the sponsor at the time such targets were chosen, but that impacted enrollment of diverse participants.

(c) ADDITIONAL CLINICAL TRIAL DATA.—The Commissioner of Food and Drugs shall issue regulations revising sections 807.92 and 814.20 of title 21, Code of Federal Regulations, to require that applications for devices approved under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) and devices cleared under section 510(k) of such Act (21 U.S.C. 360(k))whose submission includes clinical data—

(1) a description of the patient population in the United States expected to use the device, disaggregated by demographic subgroup, where such

data is available, including age group, sex, race, and ethnicity; and

(2) in summarizing the clinical investigations involving human subjects in such applications, a description of study subjects by demographic subgroup, including age group, sex, race, and ethnicity.

(d) DEADLINE FOR PROMULGATION.—The Commissioner of Food and Drugs shall issue—

(1) any proposed rules required under this section not later than 2 years after the date of the enactment of this Act; and

(2) any final rules required under this section not later than 3 years after the date of the enactment of this Act.

SEC. 3. FDA AUTHORITY TO MANDATE POSTAPPROVAL STUDIES OR POSTMARKET SURVEILLANCE DUE TO INSUFFICIENT DEMOGRAPHIC SUBGROUP DATA.

(a) DRUGS.—

(1) IN GENERAL.—Section 505(o)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(B)) is amended by adding at the end the following:

''(iv) To provide safety and effectiveness data for the drug involved for a demographic subgroup or subgroups, if—

''(I) the clinical trials conducted in support of the approval of the drug did not meet the applicable targets of enrollment, as described in section 2 of the DEPICT Act; and

''(II) in the judgement of the Secretary, additional data could inform drug labeling.''.

(2) WAIVER.—Section 505(o)(3)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(D)) is amended by adding at the end the following:

''(iii) CLINICAL TRIAL DIVERSITY ENROLLMENT.—The Secretary may not require postapproval studies or postapproval clinical trials for the purpose specified under subparagraph (B)(iv) if the sponsor provides to the Secretary a sufficient justification for not meeting the enrollment targets referred to in such subparagraph, which may include—

''(I) factors outside of the sponsor's control, such as a lack of retention of participants;

''(II) differences in the enrollment targets, disaggregated by demographic subgroup, and actual enrollment that are determined by the Secretary to be insignificant in nature;

''(III) information not available to the sponsor at the time such enrollment targets were chosen, but that impacted enrollment of diverse participants;

''(IV) potential for selection bias; and

''(V) any other reason that the Secretary determines is sufficient justification.''.

(3) USE OF REAL WORLD EVIDENCE.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following:

''(G) USE OF REAL WORLD EVIDENCE.—Real world evidence (as defined in section

505F(b)) may be used to support or satisfy the requirements under this paragraph.''.

(b) DEVICES.—Section 522(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l(a)(1)(A)) is amended—

(1) in subparagraph (A)—

(A) in clause (ii), by striking ''or'' at the end;

(B) in clause (iii)(II), by striking ''facility.'' and inserting ''facility; or''; and

(C) by adding at the end the following:

''(iv) with respect to which—

''(I) clinical studies submitted to support that approval or clearance did not meet the applicable targets of enrollment, as described in section 2 of the DEPICT Act; and

''(II) with respect to which a justification described in subparagraph (D) is not provided.''; and

(2) by adding at the end the following:

''(C) USE OF REAL WORLD EVIDENCE.—Real world evidence (as defined in section 505F(b)) may be used to support or satisfy the requirements under this paragraph.

''(D) CLINICAL TRIAL DIVERSITY ENROLLMENT.—The Secretary may not require a manufacturer to conduct postmarket surveillance under subparagraph (A) with respect to a device for the purpose specified in clause (iv) of such subparagraph if the manufacturer provides to the Secretary a sufficient justification for not meeting the enrollment targets referred to in such subparagraph, which may include—

''(i) factors outside of the manufacturer's control, such as a lack of retention of participants;

''(ii) differences in the enrollment targets, disaggregated by demographic subgroup, and actual enrollment that are determined by the Secretary to be insignificant in nature;

''(iii) information not available to the manufacturer at the time such enrollment targets were chosen, but that impacted enrollment of diverse participants;

''(iv) potential for selection bias; and

''(v) any other reason that the Secretary determines is sufficient justification.''.

(c) REPORTS FOR CERTAIN DEVICES.—The Commissioner of Food and Drugs shall issue regulations revising section 814.84 of title 21, Code of Federal Regulations, to require holders of an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) to include in the reports submitted under such section 814.84, to the extent possible, any data not previously submitted under such section 814.84 that may inform the safety and effectiveness of the device involved in underrepresented demographic subgroups.

(d) REGISTRY AND RESULTS DATA BANK INCLUSION.—Section 402(j)(1)(A) of the Public Health Service Act (282(j)(1)(A)) is amended—

(1) in clause (ii)—

(A) in subclause (I), by striking ''and'' at the end;

(B) in subclause (II), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(III) postmarket surveillance for any device as required under clause (iv) of section 522(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act.''; and

(2) in clause (iii)(I), by striking the period at the end and inserting the following: ", including any postapproval study or postapproval clinical trial for a drug as required under section 505(o)(3)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.".

(e) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, and in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, shall convene a public meeting to consider the ways by which—

(A) drug sponsors and medical device manufacturers may disseminate information to the public on clinical trial enrollment demographic data in a timely and accessible manner;

(B) drug and device sponsors, in consultation with the Commissioner of Food and Drugs, may publicly disseminate information on subgroup analyses conducted by the sponsors in cases where—

(i) such data is not sufficient for the purpose of updating drug and device labels; or

(ii) such analyses do not show significant differences between demographic subgroups; and

(C) drug and device sponsors, in consultation with the Commissioner of Food and Drugs, may collect and publicly disseminate real world evidence that may provide information on the safety and effectiveness of drugs or devices for a demographic subgroup or subgroups.

(2) REPORT.—Not later than 180 days after the date on which the public meeting is convened under paragraph (1), the Secretary shall make available on the website of the Food and Drug Administration a report on the topics discussed at such meeting The report shall include a summary of, and response to, recommendations raised in such meeting.

SEC. 4. ANNUAL REPORT ON PROGRESS TO INCREASE DIVERSITY IN CLINICAL TRIALS AND STUDIES.

(a) IN GENERAL.—Beginning not later than 2 years after the date of the enactment of this Act, and each year thereafter, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to Congress, and publish on the public website of the Food and Drug Administration, a report

that addresses progress on increasing diversity in clinical trial and study enrollment.

(b) CONTENTS OF REPORT.—The report submitted under subsection (a) shall include, with respect to applications for drugs or devices approved or cleared under sections 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), or 360e) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) during the calendar year that immediately precedes the year in which the report is submitted—

(1) an analysis of the extent to which clinical trials conducted with respect to such applications have met the demographic subgroup enrollment targets for clinical trials and studies required by the regulations amended pursuant to section 2 and the amendments made by section 3;

(2) the frequency with which enrollment targets by demographic subgroup set for a clinical trial conducted under an exemption for investigational use of a drug under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351 of the Public Health Service Act (42 U.S.C. 262) or an exemption for investigational use of a device under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g))

do not adequately reflect the incidence in the United States population of the disease or condition being studied in the clinical trial and a summary of the rationales provided for enrollment targets by demographic subgroup in such cases;

(3) a summary of the justifications sponsors provided in the cases where sponsors did not meet the enrollment targets specified pursuant to section 2, disaggregated by demographic subgroup; and

(4) the Secretary's recommendations, as appropriate, for strategies presented in such diversity plans to attain enrollment targets that should be adopted by sponsors as best practices.

(c) POSTMARKET STUDIES.—Beginning 3 years after the first instance in which the Secretary requires a the sponsor of an application for a drug or device approved or cleared under sections 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), or 360e) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to conduct postmarket studies or postmarket surveillance under clause (iv) of section 505(o)(3)(B) and clause (iv) of section 522(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (as added by subsections (a) and (b) of section

3), and each year thereafter, the report submitted under subsection (a) shall also include—

(1) the number of such applications that were required to initiate postmarket studies or surveillance in the previous calendar year under clause (iv) of section 505(o)(3)(B) and clause (iv) of section 522(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (as added by subsections (a) and (b) of section 3), the numbers of such applications that have, as of the end of the calendar year immediately preceding the year in which the report is submitted, in-progress postmarket requirements, and the number of such applications that have completed postmarket requirements for each year, beginning on the date of the enactment of this Act;

(2) an analysis of the average amount of time for completion of such postmarket requirements, disaggregated by type of application and type of postmarket requirement;

(3) an analysis of how the imposition of such postmarket requirements has impacted the availability of demographic subgroup-specific safety and efficacy data for drugs, biologics, and devices; and

(4) the Secretary's recommendations, as appropriate, for additional guidance or postmarket re-

quirements to facilitate the collection and reporting of representative demographic subgroup data in support of applications for the approval or clearance of, or updates to the labeling of, drugs and devices under sections 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), or 360e) or licensure of biological products under section 351 of the Public Health Service Act (42 U.S.C. 262).

(d) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 5. PUBLIC MEETING ON CLINICAL TRIAL FLEXIBILITIES INITIATED IN RESPONSE TO COVID-19 PANDEMIC .

(a) IN GENERAL.—Not later than 180 days after the date on which the COVID–19 emergency period ends, the Secretary of Health and Human Services shall convene a public meeting to discuss the regulatory flexibilities adopted by the Food and Drug Administration during the COVID–19 emergency period to mitigate disruption of clinical studies and clinical trials, including flexibilities detailed in the March 2020 guidance entitled ''Conduct of

Clinical Trials of Medical Products During the COVID-19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards'', and any subsequent updates to such guidance. The Secretary shall invite to such meeting representatives from the pharmaceutical and medical device industries who sponsored clinical trials and clinical studies during the COVID–19 emergency period and organizations representing patients.

(b) TOPICS.—Not later than 90 days after the date on which the public meeting under subsection (a) is convened, the Secretary shall make available on the public website of the Food and Drug Administration a report on the topics discussed at such meeting. Such topics shall include discussion of—

(1) the actions drug sponsors took to utilize such regulatory flexibilities and the frequency at which such flexibilities were employed;

(2) the characteristics of the sponsors, trials, and patient populations impacted by such regulatory flexibilities;

(3) a consideration of how regulatory flexibilities to mitigate disruption of clinical trials during the COVID–19 emergency period, including decentralized clinical trials, may have affected access to clinical studies and trials for certain patient popu-

lations, especially unrepresented racial and ethnic minorities; and

(4) recommendations for incorporating certain clinical trial disruption mitigation flexibilities into current or additional guidance to improve clinical trial access and enrollment of diverse patient populations.

(c) COVID–19 EMERGENCY PERIOD DEFINED.—In this section, the term ''COVID–19 emergency period'' has the meaning given the term ''emergency period'' in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

SEC. 6. COMMUNITY ENGAGEMENT AND OUTREACH TO IMPROVE INCLUSION OF UNDERREPRESENTED MINORITIES IN CLINICAL TRIALS AND RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct, coordinate, and support activities for purposes of community engagement with, and outreach to, underserved communities to facilitate inclusion of underrepresented minorities in clinical research and clinical trials.

(b) ACTIVITIES.—Activities conducted, coordinated, or supported under this section may be for any of the following purposes:

(1) Developing and disseminating best practices for community engagement and outreach and for inclusive participation in clinical research and trials.

(2) Creating and providing tools and educational resources—

(A) to facilitate adoption of such best practices by researchers and clinical trial sponsors; and

(B) to encourage awareness of, and participation in, clinical trials and research among underrepresented minorities;

(3) Engaging community stakeholders in underrepresented racial and ethnic minority communities and fostering partnerships with community-based organizations serving underrepresented racial and ethnical minority populations to encourage participation in clinical trials and research.

(4) Conducting and supporting community engagement research.

(c) SUPPLEMENT, NOT SUPPLANT.—Grants under this subsection shall be used to supplement and not supplant existing initiatives and programs at the National In-

stitutes of Health to improve diversity in clinical trials and research.

SEC. 7. GRANTS TO INCREASE THE CAPACITY OF COMMUNITY HEALTH CENTERS TO PARTICIPATE IN CLINICAL TRIALS AND RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the National Institutes of Health, shall award grants to, and enter into cooperative agreements with, qualified entities to increase capacity at such qualified entities to participate in clinical trials and research by—

(1) enhancing and expanding infrastructure at community health centers to support participation in clinical trials and research, including information technology improvements and the hiring and training of healthcare personnel, such as patient navigators and culturally trained site personnel to conduct, or recruit for, clinical trials;

(2) reimbursing administrative costs and patient care costs incurred by qualified entities in the course of clinical research and trials that are not otherwise reimbursable by existing payers; and

(3) implementing community education and outreach strategies.

(b) QUALIFIED ENTITIES DEFINED.—In this section, the term ''qualified entity'' means—

(1) rural health clinics, as defined in section 1861(aa)(2) of the Social Security Act (42 U.S.C. 1395x(aa)(2));

(2) federally-qualified health centers described in section 1861(aa)(4)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B));

(3) facilities operated by the Indian Health Service, an Indian Tribe, Tribal Organization, or an Urban Indian organization, as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603); and

(4) entities eligible to receive funds under section 330 of the Public Health Service Act (42 U.S.C. 254b).

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act, $100,000,000 for the period of fiscal years 2022 through 2025.