



June 9, 2022

Chairman Frank Pallone
 Energy and Commerce Committee
 US House of Representatives
 Washington DC 20515

Ranking Member Cathy McMorris Rodgers
 Energy and Commerce Committee
 US House of Representatives
 Washington DC 20515

Chairwoman Anna Eshoo
 Subcommittee on Health
 Energy and Commerce Committee
 US House of Representatives
 Washington DC 20515

Ranking Member Brett Guthrie
 Subcommittee on Health
 Energy and Commerce Committee
 US House of Representatives
 Washington DC 20515

Re: Support of NIH Clinical Trial Diversity Act (H.R. 7845)

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie:

We want to thank you for your bipartisan leadership in advancing the Food and Drug Amendments of 2022, and specifically the inclusion of Food and Drug Administration (FDA) policies to improve clinical trial diversity. We write to request that you take steps to complement these policies by enacting policies to improve clinical trial diversity across a wide range of clinical research funded by the National Institutes of Health (NIH). Our request is supported by a recent NASEM report¹ which calls for policies to improve diversity at both FDA and NIH. Specifically, we are writing in support of H.R. 7845 NIH Clinical Trial Diversity Act.

The NIH Clinical Trial Diversity bill is a bipartisan bill led by Representative Robin Kelly and her colleagues Representatives Fitzpatrick, Cárdenas, Butterfield and Clarke which builds upon NIH's current policies to enhance the inclusion of women, racially and ethnically diverse populations, and individuals across the lifespan

¹ [Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups |The National Academies Press](#)

in all NIH funded clinical trials. This bill also provides a framework for NIH to work with sponsors so they can meet their diversity goals, ensuring that NIH sponsored clinical research achieves its goal of developing treatments and interventions to address diseases and conditions with the best possible science.

Although clinical trials test the treatments that everyone takes, trial sponsors do not test those potentially promising treatments on everyone equally. Despite making up 14% of the population of the United States, less than 3% of all clinical trial participants are Black.² That small percentage becomes even more disconcerting when you consider the disproportionate burden of certain diseases. For example, Triple-Negative Breast Cancer (TNBC) is a particularly aggressive kind of breast cancer associated with more advanced stages of disease as well as high rates of relapse, metastasis, and mortality.³ Not only do Black women have a 3x higher odds of being diagnosed with TNBC, they also have a higher incidence overall, which means that there are simply more Black TNBC patients than any other ethnicity or racial group.⁴ And yet, most TNBC treatments were trialed on middle-aged white women with early-stage breast cancer.⁵

In fact, results of a recent survey presented at the American Society of Clinical Oncology's meeting showed that most Black women with diagnosed metastatic breast cancer do not get enrolled into clinical trials and just 40% of Black respondents reported being offered a trial. This is despite over 80% answering that they would consider joining a trial had they known about one.⁶

Similarly, Alzheimer's disease has been shown to have a disproportionate burden on Black and Hispanic populations with incidence rates estimated to be double among Black older adults and 1.5 times higher in Hispanic older adults compared to their older white counterparts. However, trials even as recently as last year failed to adequately enroll participants from these communities. In the pivotal clinical trials supporting FDA approval of aducanumab (Aduhelm), only 0.6% of participants identified as Black and 3% as Hispanic, while only 6 Black participants were randomized into the trial arm with the FDA approved treatment dose.⁷

As is, current medical research does not take into consideration the efficacy of new technologies across different age, sex, and racial and ethnic groups. We cannot know whether treatments work for indicated patients across age, sex, and racial and ethnic subpopulations unless they are tested in these varied subgroups. In order to test how drugs work on a wide range of people from all ages, sexes and racial and ethnic groups, we need more clinical trials that are more representative of the people most impacted by diseases.

While the health disparities seen in breast cancer and Alzheimer's disease are devastating, the same disparities exist across multiple disease states and diagnoses. We must take steps to hold clinical trial sponsors accountable and support their efforts to ensure that clinical trials include diverse participants who are reflective of the populations that are most impacted by specific diseases and conditions. To achieve this goal, the *NIH Clinical Trial Diversity Act* will:

² [Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018 | Health Disparities | JAMA Oncology | JAMA Network](#)

³ Aysola K, Desai A, Welch C, et al. Triple Negative Breast Cancer - An Overview. *Hereditary genetics: current research*. 2013;(Suppl 2): 001. <https://doi.org/10.4172/2161-1041.S2-001>

⁴ McCarthy AM, Friebel-Klingner T, Ehsan S, et al. Relationship of established risk factors with breast cancer subtypes. *Cancer Med*. 2021;10:6456–6467. <https://doi.org/10.1002/cam4.4158>

⁵ 4. 2019 Drug Trials Snapshots Summary Report. U.S. Food & Drug Administration. <https://www.fda.gov/media/135337/download>. Published 2019. Accessed July 21, 2021.

⁶ Chen, Angus. "Many Black cancer patients say they aren't offered the chance at clinical trials, survey finds." *Stat*, 06 June 2022. [Many Black cancer patients not offered access to clinical trials, survey finds \(statnews.com\)](#)

⁷ Manly, J. Jennifer, Glymour, M. Maria. What the Aducanumab Approval Reveals About Alzheimer Disease Research. *Jama Neurology*. 2021; 78(11):1205-1306. doi:10.1001/jamaneuro.2021.3404

- Require NIH to work with clinical trial sponsors to develop clear and measurable recruitment and retention goals based on disease/condition prevalence as well as a rationale for specified goals and a recruitment plan
- Ensure the availability of less burdensome follow-ups during clinical trials (e.g., phone participation, weekend hours) to increase participation of underrepresented populations
- Launch a public awareness campaign across federal agencies related to research participation opportunities

We don't have the luxury of time—too many women and men of diverse racial and ethnic groups across all ages are dying every day at the hands of a medical system that does not have the science necessary to treat them. More than that, the COVID-19 pandemic has highlighted and magnified substantial health inequities that exist in our system, including screening delays that are conservatively projected to lead to an excess of 10,000 deaths from breast cancer and colorectal cancer over the next 10 years because of the pandemic. Diverse clinical research is one step towards closing the equity gap by ensuring that treatments consider the specific needs across a range of ages, races, ethnicities, and sexes.

While the provisions included in the Food and Drug Amendments Act of 2022 are an important step towards diversifying clinical trials, there is still a need for strengthening clinical trial diversity standards at the NIH. NIH funds a variety of clinical trials, including those that will not result in a drug/therapeutic submitted for approval at the FDA, such as trials that assess behavioral interventions for mental health and substance use disorders. Therefore, HR7845 NIH Clinical Trial Diversity Act is an essential part of ensuring that the wide spectrum of clinical trial research includes diverse participants.

We respectfully request that the Energy and Commerce Health Subcommittee include the HR7845 NIH Clinical Trial Diversity Act in a legislative hearing this summer.

Thank you for the opportunity to express support for this bill. Feel free to reach out to any of the organizations below if you have questions.

Sincerely,

American Academy of Family Physicians
 American Cancer Society Cancer Action Network
 American College of Physicians
 American Medical Association
 American Psychiatric Association
 American Psychological Association
 American Medical Student Association
 Association of Black Cardiologists
 Beyond Celiac
 Doctors for America
 Generation Patient
 Leukemia & Lymphoma Society
 National Center for Health Research
 National Minority Quality Forum
 National Organization of Rare Diseases

No Health without Mental Health

Public Citizen

Society for Public Health Education (SOPHE)

Society for Women's Health Research

Susan G. Komen

TOUCH, The Black Breast Cancer Alliance

Universities Allied for Essential Medicines