

May 11, 2022

The Honorable Patty Murray
Chairwoman
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce United
States House of Representatives
Washington, D.C. 20515

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Murray, and Ranking Member Burr;

The 89 undersigned organizations, representing patients with chronic and acute health conditions, write to urge that you take bold steps to improve the diversity of enrollment in clinical trials as part of this year's Prescription Drug User Fee Act (PDUFA) reauthorization.

Today, the majority of clinical trials fail overwhelmingly to achieve diverse enrollment - despite the fact that many serious and chronic diseases disproportionately impact underrepresented racial and ethnic minority groups. This lack of diversity in trial enrollment inhibits a full understanding of how safe and effective new drugs might be across their intended populations. It also exacerbates disparities in access to treatment when enrolling in a clinical trial may be a patient's most effective treatment option.

Improving clinical trial diversity is an imperative both for patient access and comprehensive scientific research. Despite racial and ethnic minority groups comprising nearly 40% of the US population, about 75% of participants in trials for drugs approved by the FDA in 2020 were white.¹ When compared against the disproportionate burden of acute and chronic disease across racial and ethnic minority groups, this stark contrast highlights a growing problem contributing to both health and socioeconomic disparities.²

Clinical trials should be available to all patients who qualify, including those who experience barriers to care and/or those who are from underrepresented communities. Reducing barriers to clinical trial participation is also good science. As America becomes more racially and ethnically diverse, a clinical trial system that fails to enroll patients from growing demographics will not support the pace of innovation that will help us meet our potential. We urge Congress to make real and meaningful reforms that will help ensure patients in every part of the country have access to the clinical trial care they need, while at the same time accelerating the development of new and better treatment options for patients for decades to come.

¹ US Food and Drug Administration, *2020 Drug Trials Snapshots: Summary Report*, February 2021, <https://www.fda.gov/media/145718/download>

² Thorpe, KE. et al., *The United States can reduce socioeconomic disparities by focusing on chronic diseases*, August 17, 2017, Health Affairs Blog, <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full>.

Promoting Sponsor Accountability for Enrollment Diversity

We are particularly pleased that the House Energy & Commerce Committee is taking up provisions related to promoting clinical trial diversity by increasing sponsor accountability. While the FDA encourages and supports sponsors developing diversity plans with enrollment targets, trial sponsors are not required to develop or submit these plans during the FDA's trial design review processes. Clinical trial sponsors should be required to build in specific, measurable enrollment targets as part of their trial design, prior to Phase II or III trials, to ensure that enrollment includes participants reflective of the diverse populations impacted by the specific disease or condition the therapy is intended to address. Incorporating diversity planning into the trial design process at its earliest stages would ensure that underrepresented groups aren't left behind and examine all aspects of trial design and conduct to diminish barriers.

Reduce Travel Burden for Trial Participants

In many cases, underrepresented groups may be less able to travel long distances to participate in a clinical trial, either from rural areas or even within urban areas. To promote trial access for these patients, trial designs must consider delivering certain clinical trial services outside of the centralized academic medical center setting. Trial flexibilities extended by the FDA during the COVID-19 public health emergency allowed certain trial services to be provided at community health facilities or in a patient's home, including the ability to utilize telemedicine and have interim toxicity evaluation visits, as long as precautions were in place to ensure reliable data. With two years of experience under these flexibilities, it is clear that some standardized services such as phlebotomy, traditional diagnostic imaging tests, and vitals checks can be provided safely and accurately by community providers in many cases. We urge Congress to make these flexibilities permanent in order to dramatically reduce travel and cost burdens on patients and reduce a key barrier to trial enrollment and retention.

We also look forward to working with you moving forward to address other barriers to increasing clinical trial participation and diversity and respectfully offer our support of the following policies for future consideration:

Improve Outreach to Underserved Patients & Providers

Investing in community-based providers is more likely to reach patients historically underrepresented in clinical trials. Community health centers are key to breaking down the barriers between the academic medical center and the healthcare teams patients already know and trust. However, many of these community providers are already stretched thin and lack the capacity to engage their patients in clinical trial enrollment. Federal resources should be directed towards community health center grant programs that support hiring and training culturally competent on-site personnel to conduct and recruit for trials, as well as implementing the IT systems necessary to seamlessly educate and enroll patients.

Minimize Financial Barriers

The cost associated with getting to a clinical trial location and making arrangements for family members can make enrolling in a clinical trial impossible. However, current federal fraud and abuse laws discourage sponsors from paying directly for digital technologies, transportation, lodging, and meals to trial participants and their families without the threat of legal action. This disincentive should be removed, and federal rules should clarify that sponsors can provide this assistance to trial enrollees without the threat of liability.

Conclusion

As America becomes more racially and ethnically diverse, a clinical trial system that fails to enroll patients from growing demographics will not support the pace of innovation that will help us meet our potential. We urge you to take real and meaningful steps towards this future.

Sincerely,

The Leukemia & Lymphoma Society
American Cancer Society Cancer Action Network
Academy of Oncology Nurse & Patient Navigators
Accessia Health
AliveAndKickn
ALS Association
American Heart Association
American Kidney Fund
American Liver Foundation
American Lung Association
American Society for Radiation Oncology
Anxiety and Depression Association of America
Association for Clinical and Translational Science
Association for Clinical Oncology
Association of American Cancer Institutes
Association of Community Cancer Centers (ACCC)
Association of Oncology Social Work
Asthma and Allergy Foundation of America
Bladder Cancer Advocacy Network
Cancer ABCs
Cancer Support Community
CancerCare
Case Western Reserve University School of Medicine
Children's Cancer Cause
Clinical Research Forum
College of American Pathologists
Color of Crohn's & Chronic Illness
Colorectal Cancer Alliance
Dana-Farber Cancer Institute
Debbie's Dream Foundation: Curing Stomach Cancer
Digestive Disease National Coalition
Duke Health

Epilepsy Foundation
Exon Group
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Friends of Cancer Research
GBS-CIDP Foundation International
GLMA: Health Professionals Advancing LGBTQ Equality
Global Liver Institute
GO2 Foundation for Lung Cancer
Hemophilia Federation of America
ICAN, International Cancer Advocacy Network
International Myeloma Foundation
JDRF
Karen's Club
KidneyCAN
Lazarex Cancer Foundation
Livestrong
LUNgevity Foundation
Lymphoma Research Foundation
Malecare Cancer Support
Moffitt Cancer Center
National Brain Tumor Society
National Cancer Registrars Association
National Comprehensive Cancer Network
National Eczema Association
National Health Council
National Hemophilia Foundation
National Kidney Foundation
National LGBT Cancer Project
National Marrow Donor Program/Be The Match
National MS Society
National Organization for Rare Disorders
National Pancreas Foundation
National Patient Advocate Foundation
National Psoriasis Foundation

National Scleroderma Foundation
NephCure Kidney International
Oncology Nursing Society
Ovarian Cancer Research Alliance
Pennsylvania Prostate Cancer Coalition
Perelman School of Medicine, University of
Pennsylvania
Prevent Cancer Foundation
Project Sleep
Prostate Health Education Network, Inc.
Seattle Indian Health Board
Sleep Research Society
St. Baldricks Foundation

Susan G. Komen
The Consortium of MS Centers; The
International Organization of MS Nurses
The Jed Foundation
The University of North Carolina at Chapel
Hill
Tigerlily Foundation
Triage Cancer
U.S. Against Alzheimer's
wAIHA Warriors
WomenHeart: The National Coalition for
Women with Heart Disease
ZERO - The End of Prostate Cancer