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

The 71 undersigned organizations, representing patients with chronic and acute health conditions, write to urge conferees for the Prescription Drug User Fee Act (PDUFA) reauthorization to include provisions aimed at creating equitable opportunities for clinical trial participation and improving trial diversity. These principles of diverse participation and equitable access are important for both scientific and ethical reasons, yet too often clinical trials fall short.

Clinical trials serve as the bedrock of the drug development ecosystem, testing potential new interventions in a controlled setting where data are collected on the safety and efficacy of the intervention. The participants in a clinical trial typically represent a sliver of the overall population with a disease, yet findings are typically assumed to apply to the broader population. For this to be true, the trials need to represent the diversity of individuals with a given disease. Unfortunately, that is not the case today, with racial and ethnic minorities, the elderly, lower income, and rural patients routinely underrepresented. When trial populations drastically differ from the population that will ultimately use the therapy being tested, the ability to extrapolate trial findings to the real world breaks down.

We are grateful for Congress’ affirmation of the importance of clinical trial diversity through provisions already included in the House-passed version of PDUFA as well as within the PREVENT Pandemics Act. Congress now has the opportunity to ensure these provisions become law by including them in the final PDUFA reauthorization.

Meeting Patients Where They Are
While patients are seen at hospitals, practices and clinics spread throughout the communities where they live, clinical research tends to be concentrated at academic medical centers. This means that to participate in a trial, patients often have to travel longer distances. One byproduct of the COVID-19 pandemic was the rapid adoption of decentralized trial practices which reduced the need for trial participants to physically visit trial sites. Modified practices include delivering drugs to a patient’s home, allowing some tests to be done at local facilities, and allowing some monitoring visits to be conducted remotely through telemedicine visits. These same flexibilities that reduced the need for in-person visits during the pandemic also hold the potential post-pandemic to simplify clinical trial participation,
especially for those who do not have easy access to specialized research centers. FDA has allowed these flexibilities during the public health emergency, but Congress has the ability to make these permanent by directing FDA to develop permanent guidance on the use of decentralized trials in the context of promoting diverse and equitable trial participation. In addition to easing participation in trials conducted at academic sites, additional resources are needed in community sites to develop research infrastructure and outreach efforts.

**Proactive planning**
Equitable access to clinical trials and diverse participation requires deliberate planning to achieve. FDA has recently taken steps to encourage sponsors to develop diversity action plans through the release of draft guidance, but such plans are currently optional. Several provisions in the House-passed version of PDUFA would make such plans mandatory, and we urge Congress to include these diversity planning requirements in final PDUFA legislation.

**Addressing Financial Barriers**
Participation in a clinical trial often involves additional time and visits that translate into out-of-pocket costs for participants. Parking, gas, lodging and food costs mean that participants often have to spend more to be in a clinical trial, and this serves as a major barrier for lower income individuals. Similarly, in the era of decentralized trials, patients often need access to smart devices and internet connectivity in order to take advantage of remote participation via telemedicine, yet not all patients have access to needed technology. Sponsors are often willing to support participants for non-medical costs and technology but cite concern over kickback statutes as a reason for not providing such support. Congress should clarify safe harbors for sponsor provision of financial or technical support to participants in clinical trials.

America’s leadership in biomedical innovation holds great potential to improve the health of our citizens, but true progress requires that innovation work for and include every American regardless of their income, skin color or where they live. You have the power to address barriers holding back equitable clinical trial participation, and we urge you to take action.

Sincerely,

American Cancer Society Cancer Action Network
National Comprehensive Cancer Network
The Leukemia & Lymphoma Society
American Association for Cancer Research
American Heart Association
American Kidney Fund
American Liver Foundation
American Lung Association
American Society for Radiation Oncology (ASTRO)
American Society of Hematology
Arthritis Foundation
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
Breastcancer.org
CancerCare
Cancer Support Community
Children's Cancer Cause
Colorectal Cancer Alliance
Debbie's Dream Foundation: Curing Stomach Cancer
DENali Oncology Group
Epilepsy Foundation
Fight Colorectal Cancer
Florida of Society of clinical Oncology
Florida Society of Clinical Oncology
FORCE: Facing Our Risk of Cancer Empowered
Friends of Cancer Research
Global Liver Institute
GO2 Foundation for Lung Cancer
Hemophilia Federation of America
Illinois Medical Oncology Society
International Myeloma Foundation
JDRF
KidneyCAN
Livestrong
LUNGevity Foundation
Lymphedema Advocacy Group
Maryland/DC Society of Clinical Oncology
Men's Health Network
Michigan Society of Hematology and Oncology
National Brain Tumor Society
National Cancer Registrars Association
National Eczema Association
National Health Council
National Hemophilia Foundation
National Kidney Foundation
National Marrow Donor Program/Be The Match
National MS Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Oklahoma Society of Clinical Oncology
Oncology Nursing Society
Patient Access Network (PAN) Foundation
Pennsylvania Prostate Cancer Coalition (PPCC)
Prevent Cancer Foundation
Susan G. Komen
The AIDS Institute
The ALS Association
The Tigerlily Foundation
Triage Cancer
U.S. Against Alzheimer's
Winship Cancer Institute of Emory University
WomenHeart: The National Coalition for Women with Heart Disease
ZERO - The End of Prostate Cancer