July 11, 2022

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

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

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