



November 18, 2024

The Honorable Raul Ruiz
 U.S. Representative
 2342 Rayburn House Office Building
 Washington, DC 20515

The Honorable Larry Bucshon
 U.S. Representative
 2313 Rayburn House Office Building
 Washington, DC 20515

Dear Representatives Ruiz and Bucshon:

We write today on behalf of the 74 patient advocacy public health, and provider organizations below to thank you for introducing H.R. 8412, the Clinical Trial Modernization Act, and to express our support for this important legislation.

As you know, clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with cancer and other life-threatening diseases. To be successful, it is important that trials enroll an adequate number of participants that reflect the diversity of patients with the disease. However, patient enrollment in clinical trials is an ongoing challenge, and some population groups are underrepresented, including certain racial and ethnic groups, older adults, rural residents, and those with limited incomes.

We also know that concerns about potential costs of participation in a clinical trial often prevent otherwise interested patients from enrolling. For patients, clinical trial costs involve both direct medical and non-medical costs. While most insurers are required to cover the direct medical or “routine costs” of treatment ordinarily administered absent a clinical trial (e.g., standard of care diagnostic testing), patients often still have cost-sharing requirements associated with their coverage (e.g., deductibles, copays, coinsurance).

Additionally, participation in a trial can come with associated non-medical costs including transportation, lodging, and meals associated with clinic visits necessary for participation in a trial. These nonmedical costs can be especially challenging when no local trials are available and patients must travel to distant trial sites, or when there is a need for more

frequent clinic visits for additional trial-related treatment or monitoring. Patients receiving care at community cancer centers — where most cancer care is provided — have much less access to locally available clinical trials and tend to be the most affected by financial burdens of travel. These additional costs can lead to disparate participation rates between high- and low-income patients and between patients in different geographies. In fact, we know that cancer patients from households making less than \$50,000 per year are nearly 30% less likely to enroll in clinical trials.

Studies have shown that offering to reimburse patients for non-medical costs associated with trials can increase overall enrollment and may also increase participation from underrepresented groups. While some trial sponsors provide financial support for non-medical costs, those that do not often cite concerns about violating federal restrictions on providing patients with what could be viewed as a financial incentive. For patients, especially low-income patients, receipt of financial support can create challenges with potential tax burdens for any stipend-style payments, or potential disqualification from safety net programs if such trial support is considered income.

For these reasons, we are excited by the introduction of the Clinical Trial Modernization Act, which would make it easier for people to participate in clinical trials by addressing barriers they currently face. Specifically, the Clinical Trial Modernization Act:

- Removes economic barriers to increase clinical trial participation from all demographic, socioeconomic, and geographic populations by allowing sponsors to financially support trial participants for both medical (e.g., copay and co-insurance) and non-medical (e.g., travel, lodging, childcare) costs associated with trial participation.
- Facilitates remote participation in clinical trials by allowing trial sponsors to provide patients with digital health technology (e.g., smartwatch and/or tablet) necessary for participation at no cost to the patient.
- Encourages clinical trial enrollment by underrepresented groups by allowing the Department of Health and Human Services (HHS) to issue grants to support community education, outreach, and recruitment for trials, including grants to trusted messengers.
- Ensures that up to \$2,000 of non-reimbursable financial support from clinical trial sponsors provided to patients is not subject to taxation or counted against income limitations for safety net programs, which would protect 98% of cancer trial participants.

These important provisions are key to increasing clinical trial participation and, thereby, driving innovation and the development of new treatments. This benefits not only trial participants, but all of us.

Once again, we thank you for your leadership on this issue and please do not hesitate to call on us in any way that we can be supportive.

Sincerely,

American Cancer Society Cancer Action Network
 ADAP Advocacy
 African American Male Wellness Agency
 Alliance for Women's Health and Prevention
 American Association of Clinical Urologists Inc. (AACU)
 American Lung Association
 American Pharmacists Association
 American Society for Radiation Oncology
 AnCan Foundation
 Anxiety and Depression Association of America
 Asian & Pacific Islander American Health Forum
 Association for Clinical Oncology
 Association of American Cancer Institutes
 Association of Cancer Care Centers
 Biomarker Collaborative
 BLKHLTH
 Cancer Advocacy Group of Louisiana
 Caregiver Action Network
 Carolina BioOncology Institute
 Children's Cancer Cause
 Columbia University Irving Medical Center
 Debbie's Dream Foundation: Curing Stomach Cancer
 Dia de la Mujer Latina
 Epilepsy Foundation
 Exon 20 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
 GO2 for Lung Cancer
 HealthyWomen
 Hope for Heather
 ICAN, International Cancer Advocacy Network
 International Myeloma Foundation
 KidneyCAN
 Large Urology Group Practice Association (LUGPA)
 Latinas Contra Cancer
 Lazarex Cancer Foundation
 The Leukemia & Lymphoma Society

Livestrong
 LUNgevity Foundation
 Lupus Foundation of America
 Malecare Cancer Support
 MET Crusaders
 Myasthenia Gravis Association
 Myasthenia Gravis Foundation of America
 NAACP
 National Alliance for Caregiving
 National Black Nurses Association, Inc.
 National Brain Tumor Society
 National Comprehensive Cancer Network
 National Consumers League
 National Council of Urban Indian Health
 National Health Council
 National Hispanic Health Foundation
 National Hispanic Medical Association
 National Organization for Rare Disorders
 National Rural Health Association
 Oncology Nursing Society
 Ovarian Cancer Research Alliance
 PAN Foundation
 PD-L1 Amplifieds
 Pennsylvania Prostate Cancer Coalition (PPCC)
 PlusInc
 Prostate Conditions Education Council
 Prostate Health Education Network (PHEN)
 Rally Foundation for Childhood Cancer Research
 Sisters Network Inc.
 Society for Women's Health Research
 Susan G. Komen
 Tigerlily Foundation
 wAIHA Warriors
 WomenHeart: The National Coalition for Women with Heart Disease