



August 18, 2025

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

The Honorable August Pfluger  
U.S. House of Representatives  
2202 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Ruiz and Pfluger:

We write today on behalf of the undersigned 131 patient advocacy, public health, and provider organizations to thank you for introducing H.R. 3521, the Clinical Trial Modernization Act, and to express our strong support for this important legislation.

As you know, clinical trials are crucial 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 full spectrum of patients with the disease. However, patient enrollment in clinical trials is an ongoing challenge, and some population groups remain underrepresented, including certain racial and ethnic groups, older adults, rural residents, and those with limited incomes.

We also know that concerns about the 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 indirect 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 non-medical

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 the 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.<sup>1</sup>

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, the 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 reducing 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 coinsurance) 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 U.S. Department of Health and Human Services 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 federal taxation or counted against income limitations for safety net programs (e.g., Medicaid).

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.

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<sup>1</sup> Unger, Joseph M., et al. "Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study." *JAMA Oncology*, JAMA Network, Jan. 2016, [jamanetwork.com/journals/jamaoncology/fullarticle/2457394](http://jamanetwork.com/journals/jamaoncology/fullarticle/2457394).

Once again, we thank you for your leadership on this issue and please let us know how we can be supportive in advancing the bill.

Sincerely,

American Cancer Society Cancer Action Network  
Academy of Oncology Nurse & Patient Navigators  
Academy of Physicians in Clinical Research  
ADAP Advocacy Association  
Alliance for Aging Research  
Alliance for Patient Access  
Alliance for Women's Health and Prevention  
American Association of Clinical Urologists (AACU)  
American College of Chest Physicians  
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 Black Cardiologists  
Association of Cancer Care Centers (ACCC)  
Bag It Cancer  
Biomarker Collaborative  
BLKHLTH  
The Breasties  
Brem Foundation to Defeat Breast Cancer  
CancerCare  
Cancer Hope Network  
Cancer Nation (formerly the National Coalition for Cancer Survivorship)  
Cancer Support Community  
Caregiver Action Network  
Carolina BioOncology Institute  
Cheeky Charity  
Children's Cancer Cause  
CLL Society  
Colorectal Cancer Alliance  
Columbia University Irving Medical Center  
CureSearch for Children's Cancer

Debbie's Dream Foundation: Curing Stomach Cancer  
Delta for Women in Action  
Depression and Bipolar Support Alliance (DBSA)  
Diabetes Leadership Council  
Diabetes Patient Advocacy Coalition  
Dia de la Mujer Latina, INC.  
Epilepsy Foundation of America  
Exon 20 Group  
Fight Colorectal Cancer  
FORCE: Facing Our Risk of Cancer Empowered  
Friends of Cancer Research  
GBS|CIDP Foundation International  
Gerontological Society of America  
GLMA: Health Professionals Advancing LGBTQ+ Equality  
Global Liver Institute  
GO2 for Lung Cancer  
Haystack Project  
The Headache & Migraine Policy Forum  
HealthyWomen  
Highlander Health Institute  
Hope for Stomach Cancer  
ICAN, International Cancer Advocacy Network  
Infinite Strength, Inc.  
International Myeloma Foundation  
KidneyCAN  
Large Urology Group Practice Association (LUGPA)  
Lazarex Cancer Foundation  
The Leukemia & Lymphoma Society  
Life Raft Group  
Livestrong  
LUNGevity Foundation  
Lupus Foundation of America  
Lymphoma Research Foundation  
Male Breast Cancer Global Alliance  
Malecare Cancer Support

Melanoma Research Alliance (MRA)  
Men's Health Network  
MET Crusaders  
Mighty Millie Foundation  
Multiple Myeloma Research Foundation  
Myasthenia Gravis Association  
NAACP  
National Alliance for Caregiving  
National Alliance on Mental Illness (NAMI)  
National Association of Hispanic Nurses  
National Black Nurses Association, Inc  
National Bone Marrow Transplant Link  
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 (NHMA)  
National LGBT Cancer Project  
National Minority Quality Forum  
National Organization for Rare Disorders  
National Rural Health Association  
National Scleroderma Foundation  
National Urban League  
NMDP (formerly National Marrow Donor Program)  
Oncology Nursing Society  
Ovarian Cancer Research Alliance  
Pancreatic Cancer Action Network (PanCAN)  
PAN Foundation  
Patients Rising  
PDL1 Amplifieds  
Pediatric Brain Tumor Foundation  
Pennsylvania Prostate Cancer Coalition (PPCC)  
PlusInc  
Prevent Cancer Foundation  
Preventive Cardiovascular Nurses Association  
Prostate Conditions Education Council  
Prostate Health Education Network  
Pulmonary Hypertension Association  
Rally Foundation for Childhood Cancer Research  
Rare Disease Diversity Coalition  
Rural Minds  
Scout Clinical  
Sharsheret  
Sisters Network Inc.  
Society for Women's Health Research  
Stupid Cancer, Inc.  
Susan G. Komen  
Team PHenomenal Hope  
Tigertly Foundation  
TOUCH, The Black Breast Cancer Alliance  
Triage Cancer  
Unite for HER  
wAIHA Warriors  
Women As One  
WomenHeart: The National Coalition for Women with Heart Disease  
Young Adult Survivors United  
Young Survival Coalition (YSC)  
ZERO Prostate Cancer