



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.¹

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.

¹ 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.

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
Tigerlily 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