The Honorable Mike Johnson
Speaker of the House
United States House of Representatives
Washington, DC 20515

The Honorable Steve Scalise
Majority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Tom Emmer
Majority Whip
United States House of Representatives
Washington, DC 20515

The Honorable Elise Stefanik Republican Conference Chairman United States House of Representatives Washington, DC 20515 The Honorable Hakeem Jeffries
Democratic Leader
United States House of Representatives
Washington, DC 20515

The Honorable Katherine Clark
Democratic Whip
United States House of Representatives
Washington, DC 20515

The Honorable Pete Aguilar
Democratic Caucus Chairman
United States House of Representatives
Washington, DC 20515

The Honorable James Clyburn
Assistant Democratic Leader
United States House of Representatives
Washington, DC 20515

February 5, 2024

RE: Urge Support for H.R. 485: Banning QALYs in Federal Programs

Dear House Leaders,

We write as patient representatives of more than 100 patient advocacy organizations to ask each of you to **support H.R. 485**, the Protecting Healthcare for All Patients Act. This bill will protect vulnerable Americans by banning the use of Quality-Adjusted Life Years (QALY) in all federal programs.

Why do we need to ban QALY? In a time when we are demanding more evidence and scientific rigor from the treatments being developed and approved, why would we turn their coverage determination in federal programs over to an arbitrary metric? The QALY is an antiquated metric that does not meet today's scientific standards for the practice of evidence-based medicine. It is a troubling measure used to place a value on a person's life, discounting the worth of the

disabled, aged, and those living with chronic or life-threatening illnesses¹. In the simplest of terms, QALYs state that people who are very sick, old, or disabled have a lower value. Ultimately, use of QALYs translates into an ultra-utilitarian view, meaning that fewer resources should be spent on those deemed to be elderly, disabled, or sick because one year of their life is assumed to be "lower quality" and thus worth less than that of a "perfectly healthy" person.

Evidence that the QALY represents a true patient preference or value is nonexistent, perhaps because QALY was originally developed as a policy tool for rationing of healthcare services in the UK's NHS rather than as an evidence-based, patient-centric measure.² QALY values are estimated from population-level surveys around health preferences; these preference-based survey instruments can be notably problematic and have been shown to "perform inconsistently in some populations" including in patients with cardiovascular disease, the leading cause of death in the United States.³

The QALY does not represent the value of a medicine or treatment to a patient. It does not measure what it purports to measure.⁴ It is a clumsy, blunt instrument, failing to adequately capture or reflect what patients consider to be meaningful improvements in health or what patients say that they value.⁵ The full limitations and flaws of the QALY do not need to be rehashed in this letter because they are well documented in published, peer-reviewed literature by world renowned physicians, economists, and policymakers.⁶

As patients, we understand that cost must be weighed against meaningful benefit for medical innovations, but we demand that metrics used to establish a treatment's value be evidence-based, scientifically rigorous, and unbiased—just as we demand rigorous, unbiased clinical trial evidence to demonstrate safety and efficacy. The QALY is inherently biased, unscientific, and lacking in evidence that would justify its widespread use in policy. This does have a direct impact on patients—we have seen real-world examples of state Medicaid

¹Schneider, P. The QALY is ableist: on the unethical implications of health states worse than dead. Qual Life Res 31, 1545–1552 (2022). https://doi.org/10.1007/s11136-021-03052-4

² MacKillop E, Sheard S. Quantifying life: Understanding the history of Quality-Adjusted Life-Years (QALYs). Soc Sci Med. 2018 Aug;211:359-366. https://pubmed.ncbi.nlm.nih.gov/30015244/

³ Finch, A.P., Brazier, J.E. & Mukuria, C. What is the evidence for the performance of generic preference-based measures? A systematic overview of reviews. Eur J Health Econ 19, 557–570 (2018). https://doi.org/10.1007/s10198-017-0902-x

⁴ Gafni A. The quality of QALYs (quality-adjusted-life-years): do QALYs measure what they at least intend to measure? Health Policy. 1989 Oct;13(1):81-3. doi: 10.1016/0168-8510(89)90112-7. PMID: 10296157.

⁵ Hirpa M, Woreta T, Addis H, Kebede S (2020) What matters to patients? A timely question for value-based care. PLoS ONE 15(7): e0227845. https://doi.org/10.1371/journal.pone.0227845

⁶Pettitt, David & Raza, Sajid & Smith, James. (2016). The Limitations of QALY: A Literature Review. Journal of Stem Cell Research & Therapy. <u>06</u>. <u>10</u>.4172/2157-7633.1000334.

programs citing QALY-based reports to attempt to justify discrimination against patients based on a disability.

Congress must be looking to the future and doing everything in its power to ensure the 21st century treatments and cures available now, and those on the horizon, are valued with unbiased and scientific 21st century instruments, not a 50-year old tool that has never been truly fit for this purpose. We should be looking for ways to measure value based on what it actually means to a patient, and not what we think it should mean to a patient.

Fortunately, innovations in drug pricing mechanisms and outcomes measurement are likely to make the QALY obsolete in coming years. Outcomes Based Agreement programs that align incentives and reward meaningful clinical outcomes for new therapies are just one example of such innovations. The ongoing interest and excitement of policymakers, pharmaceutical manufacturers, hospital groups, and health insurers around such programs highlight that these types of value-based arrangements are the future, representing a patient-centric way to expand access to medicines and control costs. These represent just one new approach, but indicate that there are many possible ways that patients, physicians, pharma, and payers could work together to find solutions that are patient-centric and make sense for specific situations and conditions while creating win-win solutions. The QALY—by placing a restrictive value on the life of a patient, rather than seeking to maximize the value of healthcare dollars to achieve meaningful outcomes—is a relic of the past and creates losing situations for patients.

We should be looking at measures of patient satisfaction and value based outcomes of medicine, rather than placing a value on the life of the *type of patient* before a medicine is even approved.

We urge you and your colleagues to support and advance the Protecting Healthcare for All Patients Act (H.R. 485) and ban the use of Quality-Adjusted Life Years (QALY) in all federal programs.

We commend each of you for your ongoing efforts to make sure the access needs of our most vulnerable patients remain a priority and appreciate your leadership and support on this critical patient issue.

| Sincerely, | |
|----------------|--|
| Aimed Alliance | |

²https://pink.pharmaintelligence.informa.com/PS147749/Cell-And-Gene-Therapy-OutcomesBased-Contracts-In-Medicaid-Need-National-Support-HHS-Says

Akari Foundation

Alliance for Aging Research

Alliance for Patient Access

Alpha-1 Foundation

AMAC Action

American Association of Kidney Patients

American Association of People with Disabilities

American Association on Health and Disability

American Behcet's Disease Association (ABDA)

Autistic People of Color Fund

Autistic Women & Nonbinary Network

Autoimmune Association

Autoinflammatory Alliance

Avery's Hope

Best Day Ever Foundation

CancerCare

Cancer Support Community

Caregiver Action Network

Caring Ambassadors Program

Center for Autism and Related Disorders

Center for Medicine in the Public Interest

Children with Diabetes

Chronic Care Policy Alliance

Chronic Disease Coalition

Coalition of Texans with Disabilities

Color of Gastrointestinal Illnesses

Cutaneous Lymphoma Foundation

Cystic Fibrosis Research Institute

Davis Phinney Foundation for Parkinson's

Dementia Alliance International

Derma Care Access Network

Diabetes Leadership Council

Diabetes Patient Advocacy Coalition

Disability Law Center

Disability Rights California

Disability Rights Center New Hampshire

Disability Rights Iowa

Disability Rights Montana

Disability Rights North Carolina

Disability Rights Pennsylvania

Disability Rights South Carolina

Disability Rights Vermont

Disability Rights Washington

EB Legal Aid Society

Equip for Equality

Free2Care

Galatosemia Foundation

Genetic Alliance

Global Colon Cancer Association

Global Healthy Living Foundation

GO2 for Lung Cancer

Hawaii Disability Rights Center

Headache and Migraine Policy Forum

Hereditary Angioedema Association

HIV + Hepatitis Policy Institute

I AM ALS

ICAN, International Cancer Advocacy Network

Infusion Access Foundation

Kentucky Protection and Advocacy

Lakeshore Foundation

Lewy Body Dementia Association

Looms for Lupus

LuMIND IDSC

Lupus and Allied Diseases Association

Lupus Foundation of America

Mental Health America

MLD Foundation

Myasthenia Gravis Foundation of America

Myositis Support and Understanding

National Alliance for Caregiving

National Association for Continence

National Diability Rights Network

National Down Syndrome Society

National Scleroderma Foundation

Neuropathy Action Foundation

Nevada Disability Advocacy and Law Center

North Dakota Protection and Advocacy Project

Ohio Council for Cognitive Health

Partnership to Advance Cardiovascular Health

Partnership to Fight Chronic Disease

Partnership to Improve Patient Care

Patients Rising

Patients Rising Now

Pioneer Institute

Practicing Physicians of America

Prevent Blindness

PXE International

Rare Access Action Project (RAAP)

Second Wind Dreams

Special Operations Association of America (SOAA)

SSADH Association

Support for People with Oral and Head and Neck Cancer (SPOHNC)

Survivors for Solutions

SYNGAP1 Foundation

Texas Rare Alliance

The Akari Foundation

The Bonnell Foundation

The Coelho Center for Disability Law, Policy and Innovation

The Foundation to Eradicate Duchenne

The PERT Consortium

The Waiting Room Entertainment

Triage Cancer

U.S. Pain Foundation

cc: The Honorable Cathy McMorris Rodgers, Chair, Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, Energy and Commerce Committee
The Honorable Jason Smith, Chairman, Ways and Means Committee
The Honorable Richard Neal, Ranking Member, Ways and Means Committee
The Honorable Michael Burgess, M.D.

The Honorable Brad Wenstrup, M.D.