

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

The Honorable Hakeem Jeffries
Democratic Leader
United States House of Representatives
Washington, DC 20515

The Honorable Steve Scalise
Majority 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 Tom Emmer
Majority 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 Elise Stefanik
Republican Conference 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](https://pubmed.ncbi.nlm.nih.gov/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*. [06. 10.4172/2157-7633.1000334](https://doi.org/10.4172/2157-7633.1000334).

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.⁷ 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

⁷<https://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 Disability 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.