United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

March 1, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

As longtime advocates for individuals with disabilities, along with older Americans, we write to express serious concerns with the growing use of quality-adjusted life years (QALYs) and other discriminatory value assessment metrics, including in the context of federal health care programs. While recent decades have seen countless life-saving and life-enhancing advances in treatments and cures for conditions affecting vulnerable communities and seniors, the rise in QALYs risks reversing these trends, particularly as the government bureaucracy plays an increasing role in cost-effectiveness analyses for new medications under the partisan Inflation Reduction Act (IRA).

As outlined in an extensive 2019 report from the National Council on Disability (NCD), "QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities."[1] NCD also notes that "QALY calculations are subject to several methodological flaws that seriously undermine their use as a fair method of comparing the relative value of treatments." The organization reiterated this perspective in a 2021 letter to Congress, urging policymakers to ban the use of QALYs explicitly, and referencing "[t]he history of restricted access occurring in countries utilizing QALY-based cost effectiveness research raised concerns that its use in the U.S. would result in rationing care to seniors and people with disabilities."[2]

Advocates for patients and caregivers from all walks of life have echoed similar concerns, as illustrated across dozens of comments submitted to the Institute for Clinical and Economic Review (ICER), an organization that relies heavily on QALYs and other comparable benchmarks in developing value assessments for new medical technologies. The Arthritis Foundation, for instance, points to "the near-universal concerns among the patient community on using QALYs," and the National Organization for Rare Disorders contends that "ICER's current QALY model does not adequately capture the views of patients, particularly patients living with rare diseases."[3]

[1] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[2] https://ncd.gov/publications/2021/ncd-letter-qaly-ban
[3] https://icer.org/wp-content/uploads/2020/10/2020_VAF_Public_Comments_013120-1.pdf

Warnings from abroad around the use of cost-effectiveness analysis frameworks along these lines warrant urgent attention from policymakers in the United States. To name just two of the many cautionary tales from Europe, the United Kingdom's price-fixing systems for drugs, which incorporate QALYs,[4] face "a potential crisis,"[5] and Germany's drug pricing reforms have seen numerous manufacturers withdraw their products altogether,[6] including in cases where the country represented a given medication's largest market.[7] As a result, patients have suffered the consequences. As explained in a recent *Wall Street Journal* editorial, "About 85% of new medicines launched between 2012 and 2021 were available in the U.S., compared to 61% in Germany, 59% in the U.K. and 52% in France and Italy."[8]

In order to avoid a similar fate and maintain its current global leadership in biomedical research and development, the U.S. must take proactive steps to prevent bureaucratic price controls from constraining patient access to new treatments or leveraging metrics that devalue the lives of those living with rare diseases, as well as older Americans and individuals with disabilities. These efforts need not fall along partisan lines. During a recent House Energy and Commerce Health Subcommittee hearing, for instance, Members from both parties called for ending government reliance on QALYs in health care programs,[9] and nonpartisan advocacy groups have led the charge for prohibiting discriminatory cost-effectiveness measures for years.

With these concerns in mind, we urge your agencies to eliminate the use of QALYs and other similar metrics in federal programs, including in the implementation of the IRA's price-setting program. While the law enacted last summer includes non-discrimination language, any administrative guidance or regulations regarding the initiative's administration should make the ban on QALYs and benchmarks that raise comparable issues explicit and direct. We request that your agencies provide us, in writing, with specific steps and plans you have taken or intend to take in order to effectuate, in clear terms, a prohibition of this type. We also request information on avenues for direct patient and caregiver engagement in the IRA's price-setting process. Please provide us with responses by the close of business on March 3, 2023.

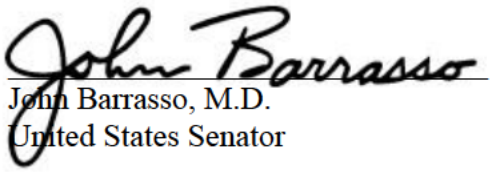
If you have questions about this request, please contact Conor Sheehey of the Senate Finance Committee staff.

Sincerely,

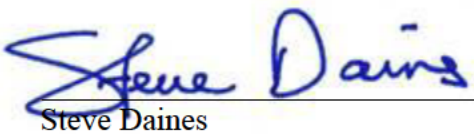
Mike Crapo
United States Senator

Thom Tillis
United States Senator

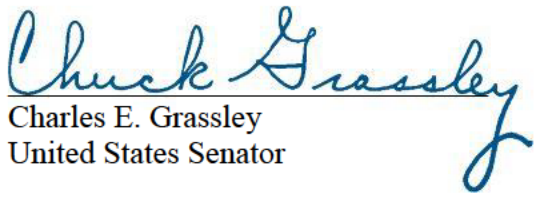
[4] https://www.nice.org.uk/glossary?letter=q
[5] https://www.forbes.com/sites/joshuacohen/2023/01/19/uks-voluntary-scheme-for-branded-medicines-pricing-and-access-vpas-faces-a-potential-crisis/?sh=543e2ae777c3
[6] https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-018-0209-3
[7] https://www.reuters.com/article/eisai-germany/japans-eisai-pulls-drug-from-germany-after-pricing-row-idUSL5N0F11XT20130625
[8] https://www.wsj.com/articles/the-wests-drug-self-sabotage-europe-pharmaceutical-investment-price-controls-treatments-covid-cancer-pfizer-11674409032
[9] https://republicans-energycommerce.house.gov/events/lives-worth-living-addressing-the-fentanyl-crisis-protecting-critical-lifelines-and-combatting-discrimination-against-those-with-disabilities



John Barrasso, M.D.
United States Senator

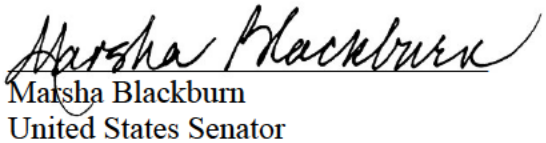


Steve Daines
United States Senator

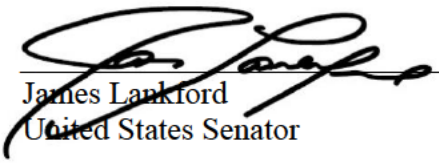


Charles E. Grassley
United States Senator

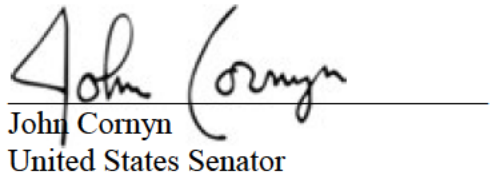
Tim Scott
United States Senator



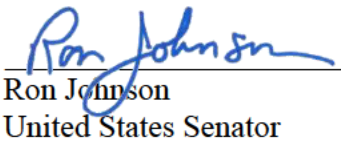
Marsha Blackburn
United States Senator



James Lankford
United States Senator



John Cornyn
United States Senator



Ron Johnson
United States Senator