

As the Chairman of the Partnership to Improve Patient Care (PIPC), I am writing with concerns about provisions in new House drug pricing legislation that have detrimental implications for patients and people with disabilities. Having been a primary author of the Americans with Disabilities Act, a member of Congress and a person with epilepsy, I recognize how challenging it is to address health care affordability. Congress can and should act to help patients afford their health care, whether it is a high-priced drug or a high-cost hospital visit. Unfortunately, the bill takes an approach that is entrenched in controversial comparative clinical and cost effectiveness standards that force patients and people with disabilities into “one-size-fits-all” decisions about their health.

This bill places hard-fought existing patient protections under serious threat. **First, it authorizes national determinations of value to be based on comparative or cost effectiveness standards that ignore differences in patient needs and discriminate against vulnerable subgroups of patients and people with disabilities, opening the door to reliance on assessments like those conducted by the Institute for Clinical and Economic Review (ICER).**

Second, it relies on policy decisions made in other countries that we know establish prices based on discriminatory cost-effectiveness standards (such as Quality-Adjusted Life Years or QALYs) and similar average metrics. Whether done directly or through reliance on decisions made by foreign countries, outmoded standards of comparative and cost effectiveness provide a poor model for ensuring access to care for patients with the greatest health care needs. In fact, use of these standards are well known to severely limit access to treatments for residents in the countries referenced in this legislation.

Third, it lacks any reference to existing statutory safeguards against misuse of QALYs and similar average metrics. We have fought a long, and often trying, battle to protect patients from facing new access barriers through misuse of comparative and cost effectiveness standards, and to keep QALYs and similar metrics from being used in policy decisions affecting coverage and access to innovative treatments. In 1992, people with disabilities succeeded in fighting a state waiver that would have used a methodology for determining access to care that was inherently discriminatory, and in 2010, Congress enacted a law to bar the use of QALYs and similar metrics in Medicare.

To be clear, we are not fooled by legislative language authorizing use of flawed cost-effectiveness standards under the guise of “comparative effectiveness analysis” and reliance on other countries’ decisions based on these standards. We’re all for making drugs more affordable, but not in ways that force patients into policies that ignore their individual differences and value.

Instead of pursuing this policy that puts patient access at risk, policymakers should pursue alternative solutions that strengthen, rather than undermine, vital patient protections. **We hope policymakers will ensure that their proposals improve care and affordability for patients, adopt and extend safeguards in current statute that prohibit application of discriminatory cost-effectiveness thresholds in Medicare (whether done overtly by Medicare or covertly via “comparative**

effectiveness analysis” or reference to foreign countries’ use of these thresholds) and codify criteria for patient-centeredness called for in CMMI’s statute. Without these patient protections, patients and people with disabilities will have little power to prevent the expanded use of one-size-fits-all value judgements that inevitably limit access to high quality innovative treatments.

As a coalition, PIPC’s mission is centered around driving a patient and person centered healthcare system. Our focus has always been on ensuring the patient voice in research and policies supporting an informed, non-discriminatory health system. Therefore, we cannot support Title 1 of this bill.

Please feel free to reach out with any questions.

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive style with a stylized initial.

Tony Coelho
Chairman

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