

ICER Analyses Based on the QALY Violate Disability Nondiscrimination Law

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Introduction

Over the past several decades, the debate over the cost of pharmaceuticals and the perceived “value” of certain drug treatments has amplified. In pursuit of cost containment, policymakers have wrestled with the concept of cost-effectiveness and sought measures by which to guide health care payers (whether Medicare, Medicaid, or private health insurers) in their decisionmaking regarding formularies and utilization management. One measure in use by many payers is the Quality-Adjusted Life Year (“QALY”). The QALY is a metric that, in theory, measures the degree to which a drug or therapy extends life and improves quality of life. The QALY is used to develop guidelines on the economic “value” of a given pharmaceutical, which then informs a payer’s decision of whether to cover such drug and, if so, under what terms—influencing cost sharing, utilization management and other payer decisions. Unfortunately, the QALY relies on a set of discriminatory assumptions that devalue life with a disability, disadvantaging people with disabilities seeking to access care based on subjective assessments of quality of life.

In a recent report commissioned for the Institute for Clinical and Economic Review (“ICER”), an organization specializing in clinical cost-effectiveness analyses relying on the QALY, Epstein, Becker & Green, P.C. posit that the use of QALY as a measure of the cost-effectiveness of specific drugs and therapies “poses absolutely no risk of

discrimination against any patient group.”¹ The Disability Rights Education and Defense Fund (“DREDF”) strongly disagrees with this conclusion.

In arriving at its bold assertion, the Epstein Becker Report relies on an erroneous interpretation of U.S. Supreme Court caselaw and irrelevant precedent from a handful of U.S. Courts of Appeals. It fails to both adequately analyze the impact the use of the QALY has on people with disabilities, and the evolving case precedent establishing the actionability of discriminatory health care benefit designs. In this paper, DREDF challenges the factual and legal assumptions that the Epstein Becker Report relies on and explains how the use of the QALY, even in tandem with alternative measures such as the Equal Value of Life Years Gained (“evLYG”), violates disability nondiscrimination law.

I. HOW THE QALY DEVALUES LIFE WITH A DISABILITY AND REDUCES COVERAGE OF TREATMENTS DISPROPORTIONATELY RELIED ON BY PEOPLE WITH DISABILITIES

The Quality-Adjusted Life Year (“QALY”) is a metric utilized by ICER and various entities that rely upon its analysis that—at least in theory—measures the degree to which a drug or therapy extends life and improves quality of life. Life-extension, however, is “adjusted” (or rather, devalued) to take into account the perceived quality of life associated with a given health status and level of impairment, typically determined through the perceptions of the general public. ICER uses the QALY in an attempt to

¹ Frank C. Morris & Alison Gabay, EPSTEIN BECKER & GREEN, P.C., *ICER Analyses and Payer Use of Cost-effectiveness Results Based on the QALY and evLYG Are Consistent With ADA Protections for Individuals with Disabilities at 7*, available at <http://icer-review.org/wp-content/uploads/2020/03/ICER-Analyses-and-Payer-Use-of-Cost-effectiveness-Results-Based-on-the-QALY-and-evLYG-Are-Consistent-With-ADA-Protections-for-Individuals-With-Disabilities.pdf> (hereinafter “Epstein Becker Report”).

measure the therapeutic value of specific drugs and treatments relative to their cost and, ultimately, make recommendations as to whether payers should cover certain pharmaceuticals and, if so, at what cost.

QALYs rely on a system of utility weights associated with particular health states. These weights assign life with a particular disability a decimal number between 0 and 1, typically calculated by eliciting the preferences of the general population. While there are different techniques used to assign weights to particular health states, the most common—the EuroQol-5 Dimensional or “EQ-5D”—asks five questions related to mobility, self-care, usual activities, pain/discomfort, and anxiety/mental health.² The answers to this questionnaire are then used to calculate an individual’s level of impairment, based on their responses to each of these five questions. Members of the public in a given country are then surveyed to assign each level of impairment a utility score, typically through questions making use of the time-tradeoff method (asking respondents to choose between living life in perfect non-disabled health for a shorter period of time as compared to living life with a given level of impairment over a longer period, trading off years of life to avoid particular levels of impairment).³ Some utility elicitation methods make use of other tools, such as the standard gamble methods (“asking respondents to choose between the certainty of life in a given level of impairment and a gamble that offers the possibility of perfect health and the possibility of death, with

² See Gianluigi Balestroni & Giorgio Bertolotti, *EuroQol-5D (EQ-5D): an instrument for measuring quality of life*, 78 MONALDI ARCH. CHEST DIS., no. 3, at 155–59 (Sept. 2012).

³ Mark Oppe, et al., *EuroQol protocols for time trade-off valuation of health outcomes*, 13 PHARMACOECONOMICS, no. 10, 993–1004 (2016).

valuation determined based on the relative size of each probability”).⁴ One year of perfect non-disabled health would equal 1 QALY; being dead would equal 0 QALY. A year with anything less than perfect health would typically result in a QALY score somewhere between 0–1 (1 minus the utility weight). In some cases, weights exceed 1, meaning that a particular level of disability is considered so severe under the QALY framework that people with certain disabilities receive a QALY score of less than 0, suggesting that life in such a health state is considered worse than death (unsurprisingly, individuals in such health states frequently disagree with this assessment).⁵

Entities engaged in value assessment, such as ICER, make use of the QALY to determine whether a given drug or therapy for persons with a given condition should be covered at a particular price. While such assessments are typically conducted in the aggregate (that is, to evaluate the value of coverage of and/or cost of a certain treatment for the entire relevant patient population, instead of for individual treatment decisions), they nonetheless have meaningful individual effects in that QALY assessments can influence what interventions will be available and under what terms they will be offered, their placement within formulary cost-sharing tiers, and utilization management decisions. Because the QALY has the effect of devaluing treatments that offer life-extension for people with ongoing disabilities or chronic conditions, it places such individuals at a serious disadvantage. For individuals with disabilities that will not be cured by medical

⁴ Sylvie M. C. van Osch & Anne M. Stiggelbout, *The construction of standard gamble utilities*, 17 HEALTH ECONOMICS, no. 1, 31–40 (Jan. 2008).

⁵ Leida M. Lamers, *The Transformation of Utilities for Health States Worse than Death: Consequences for the Estimation of EQ-5D Value Sets*, 45 MED. CARE, no. 3, 238–44 (2007); Lars Bernfort, et al., *People in states worse than dead according to the EQ-5D UK value set: would they rather be dead?*, 27 QUALITY OF LIFE RSCH., no. 7, 1827–33 (2018).

intervention, extending their lives will be worth less under the QALY framework, resulting in a lower acceptable level of reimbursement by payers (such as health insurance plans), thus reducing the likelihood that life-extending treatments for people with disabilities will be covered or, if they are, making it more likely that they will only be made available with increased cost sharing or utilization management.

The problem is that the QALY equation relies on a baseline of “perfect health” that is calculated by society’s conception of health and functioning.⁶ Having a chronic illness or disability will count against an individual’s QALY score, even if an individual considers themselves to have a high quality of life. Indeed, there is a broad literature suggesting that people with disabilities typically experience far higher quality of life than that which is perceived by the non-disabled population.⁷ This is because society undervalues life with a disability. Members of the general public often confuse “disability” with “health,” in the sense that disability is viewed as a medical disorder rather than a socially imposed condition.⁸ Because the survey profile of the U.S. undervalues a disabled person’s quality of life, this devaluation is then reflected in the utility value and thus, the QALY.

⁶ See *Quality-Adjusted Life Years and the Devaluation of Life with Disability*, NATIONAL COUNCIL ON DISABILITY, BIOETHICS & DISABILITY REPORT SERIES (Nov. 6, 2019), available at https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf (hereinafter “NCD Report”).

⁷ Peter A. Ubel, et al., *Whose quality of life? A commentary exploring discrepancies between health state evaluations of patients and the general public*, 12 QUALITY OF LIFE RSCH., no. 6, 599–607 (2003); Joseph A. Stramondo, *Bioethics, Adaptive Preferences, and Judging the Quality of a Life with Disability*, 47 SOC. THEORY & PRACTICE, no. 1, 199–220 (2021), available at <https://doi.org/10.5840/soctheorpract202121117>.

⁸ See Ubel, *supra* note 7; Stramondo, *supra* note 7; Silvia Yee, Mary Lou Breslin, et al., *Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity*, NAT’L ACADS. SCI., ENG’G, & MED. (2017), available at <http://nationalacademies.org/hmd/Activities/SelectPops/HealthDisparities/Commissioned-Papers/Compounded-Disparities>.

ICER has attempted to fix this problem by developing an alternative measure to the QALY: the Equal Value of Life Years Gained (“evLYG”). The evLYG differs from the QALY in that it only considers the *quantity* of life extension that a given drug or treatment will afford an individual, without discounting on the basis of utility weights – essentially, it provides for undiscounted life years. Use of the evLYG eliminates the risk of undervaluing life-extension for people with disabilities. However, this comes with an unacceptable price. The structure of the QALY makes use of the same weighting scheme for indicating improvements or reductions in quality of life as it does for indicating the value to ascribe to life-extension. Because the evLYG still makes use of the same methodological framework as the QALY, by eliminating discounting of life-extension it also affords no value to quality-of-life improvements, as it has no mechanism to ascribe value to symptom reduction without discounting the value of life-extension.⁹ As a result, it has limited usefulness in evaluating the value of a treatment. Contrary to the implication in the Epstein Becker Report, ICER does not combine the QALY and evLYG into a hybrid model; instead, ICER calculates the measures independently and then recommends the results of one or the other. Thus, adding the evLYG is not a solution; it merely forces payers to choose between one measure that undervalues life extension (the QALY) and one that affords no value to quality of life improvements (the evLYG). Neither accounts for both the full value of life-extension and the value of quality of life improvement.

For example, consider the coverage of the pharmaceutical used to treat cystic fibrosis (“CF”), a genetic disease that causes thickened mucus, which progressively

⁹ Anirban Basu, et al., *Health Years in Total: A New Health Objective Function for Cost-Effectiveness Analysis*, 23 VALUE HEALTH, no. 1, 96–103, 97–98 (2020).

blocks an individual's respiratory and digestive systems and eventually causes death. Until recently, there were no drugs to effectively treat CF; there were only treatments for its symptoms. In 2019, building on several more modest CF treatments approved in the years prior, the U.S. Food and Drug Administration ("FDA") approved the drug Trikafta (Elexacaftor/Ivacaftor/Tezacaftor), which partially restores functioning of the defective protein that causes CF and offers a dramatic improvement over all prior options available to treat the condition.¹⁰ While many people with CF have notable functional limitations and may spend a significant amount of time in the hospital each year, they also report a generally high quality of life.¹¹ Despite this, the U.S. country survey severely devalues quality of life with decreased lung function,¹² playing a role in ICER's overinflated cost-to-QALY ratio for the drug Trikafta (apx. \$1,100,00 per QALY¹³). This assessment makes it significantly less likely that payers will cover Trikafta, leaving people with CF without effective long-term treatment options and increasing the likelihood that payers will impose burdensome utilization management on the drug, presenting serious administrative burdens for people with CF seeking to access it. The use of the evLYG will not correct this problem—while the evLYG no longer discounting Trikafta's predicted longevity

¹⁰ FDA, *FDA approves new breakthrough therapy for cystic fibrosis* (October 21, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-breakthrough-therapy-cystic-fibrosis>.

¹¹ NAT'L INST. FOR HEALTH & CARE EXCELLENCE, *Single Technology Appraisal: Lumacaftor and Ivacaftor Combination Therapy for Treating Cystic Fibrosis Homozygous for the F508del Mutation* (February 2016), available at <https://www.nice.org.uk/guidance/ta398/documents/committee-papers>; UK CYSTIC FIBROSIS TRUST, *UK Cystic Fibrosis Treasury: Annual Data Report 2017* (August 2018).

¹² INST. FOR CLINICAL & ECONOMIC REVIEW, *Modulator Treatments for Cystic Fibrosis: Effectiveness and Value* (April 27, 2020), available at https://icer.org/wp-content/uploads/2020/08/ICER_CF_Evidence_Report_042720.pdf.

¹³ *Id.* at ES12.

benefit will reduce its projected cost, this is offset by the evLYG's failure to take into account any quality of life improvements that the drug, or any other drug being evaluated via the evLYG method, may bring to a person with a disability. Adding the evLYG is irrelevant to fixing the QALY; it simply forces a tradeoff between considering quality or undiscounted length of life, when appropriate valuation should take both such measures into account.

II. HOW RELIANCE ON THE QALY VIOLATES DISABILITY NONDISCRIMINATION LAW

The Americans with Disabilities Act,¹⁴ Section 504 of the Rehabilitation Act,¹⁵ and Section 1557 of the Affordable Care Act¹⁶ prohibit covered entities, including virtually all U.S. healthcare providers and payers (including public and private health care insurers),¹⁷ from subjecting qualified individuals with disabilities to discrimination in their health care programs and activities. As recognized by the U.S. Supreme Court, disability law reaches not only discrimination that is the result of “invidious animus,” but also of

¹⁴ 42 U.S.C. §§ 12101–12213 (2010).

¹⁵ 29 U.S.C. § 794.

¹⁶ 42 U.S.C. § 18116.

¹⁷ Medical providers, offices, and hospitals operated by a state or local government are subject to Title II of the ADA. *See id.* §§ 12131(1); *see also* 28 C.F.R. Part 35, App. B, § 35.102. Private medical providers, offices, and hospitals are subject to Title III of the ADA. *See* 42 U.S.C. §§ 12181(7)(F), 12182(a); *accord* 28 C.F.R. § 36.104. All healthcare providers and facilities that accept federal financial assistance (including Medicare and Medicaid reimbursements) and all facilities operated by federal agencies are covered by Section 504 of the Rehabilitation Act. *See* 29 U.S.C. § 794. All health care programs and activities, any part of which accept federal financial assistance (including most private healthcare providers and insurance companies), are subject to Section 1557 of the ACA. 42 U.S.C. § 18116.

“thoughtlessness,” “indifference,” and “benign neglect.”¹⁸ Section 504 implementing regulations also make clear that illegal discrimination includes providing “an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement” as that provided to people without disabilities;¹⁹ and also “eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any service, program, or activity.”²⁰

A. Disability Nondiscrimination Law Prohibits Discriminatory Benefit Designs

A health insurance practice or policy violates disability nondiscrimination law if it denies people with disabilities “meaningful access” to a health care benefit.²¹ In *Alexander v. Choate*, the U.S. Supreme Court, evaluating a proposed reduction in the number of annual inpatient hospital days covered by a State Medicaid program, held that Section 504 permits claims of disparate impact or effect in the health care setting when a policy denies “meaningful access” to a benefit.²² In *Choate*, a class of Tennessee Medicaid recipients argued that a proposed 14-day limitation on hospitalization—or *any* annual limitation on inpatient days, for that matter—would have a disproportionate effect on Medicaid recipients with disabilities.²³ The Court, evaluating the claim, explained: “The

¹⁸ See *Alexander v. Choate*, 469 U.S. 287, 296–99 (1985) (holding that Section 504’s objectives would be “difficult if not impossible to reach” were it construed to not permit claims of disparate impact); *Crowder v. Kitigawa*, 81 F.3d 1480, 1484–85 (9th Cir. 1996).

¹⁹ 28 C.F.R. § 35.130(b)(1)(iii) (2010).

²⁰ *Id.* § 35.130(b)(8).

²¹ See *Choate*, 469 U.S. at 301.

²² *Id.* at 296–99.

²³ *Id.* at 290.

benefit itself, of course, cannot be defined in a way that effectively denies otherwise qualified handicapped individuals the meaningful access to which they are entitled; to assure meaningful access, reasonable accommodations in the grantee's program or benefit may have to be made."²⁴ While the Court rejected the plaintiffs' particular disparate impact claim,²⁵ it expressly acknowledged that other healthcare policies or practices could violate disability nondiscrimination law.²⁶ In particular, it emphasized that policies that "apply to only particular handicapped conditions;" those that "take[] effect [based on a] particular cause of hospitalization[;]" or those that prevent conditions "uniquely associated with the handicapped or occurring with greater frequency among them" from being "effectively treated, at least in part," could violate Section 504.²⁷

The Epstein Becker Report erroneously concluded that *Choate* stands for the proposition that disability discrimination claims are not actionable when they are based on the "content" of a health benefit policy (as opposed to the ability to "access" the

²⁴ *Id.* at 301

²⁵ *Id.* at 298–300, 308. The Court found that the 14-day policy did not give rise to the type of disparate impact cognizable under Section 504 because it did not have a "particular exclusionary effect" on disabled insureds. *Id.* at 302. It explained: "[The policy] does not distinguish between those whose coverage will be reduced and those whose coverage will not on the basis of any test, judgment, or trait that the handicapped as a class are less capable of meeting or less likely of having." *Id.* Additionally, there was nothing in the record suggesting that disabled insureds could not meaningfully benefit from 14 days of inpatient coverage. *Id.* "The record does not contain any suggestion that *the illnesses uniquely associated with the handicapped or occurring with greater frequency among them cannot be effectively treated*, at least in part, with fewer than 14 days' coverage," it explained. *Id.* at 302 n.22 (emphasis added). To the contrary, the Court explained, the evidence showed that the 14-day rule would "fully serve 95% of [disabled Medicaid recipients]." *Id.* at 303.

²⁶ *See id.*

²⁷ *Id.* at 302 n.22.

benefit). To support this conclusion, the Report cited a line in *Choate* stating that the purpose of the Medicaid Act was not to provide “adequate health care.” Contrary to the one-paragraph analysis provided by Epstein Becker, the Supreme Court did *not* foreclose disability discrimination claims based on the “content” of a health benefit policy in *Choate*; instead, it engaged in a nuanced analysis that looks to the underlying purposes of the statute at issue to define the nondiscrimination standard. Here, the Supreme Court, based on the evidence at hand, held that the remedies sought by the *Choate* plaintiffs, including a prohibition on *any* durational limit on hospitalization days, went beyond the “meaningful access” that State Medicaid plans are required to provide under the Medicaid Act. It reasoned that such remedies were unsupported by the Medicaid Act’s legislative intent and would impose a “virtually unworkable” requirement on the State Medicaid administrators, who would be forced to engage in a balancing of all potential harms and benefits to disabled insureds before making any coverage change.²⁸ Central to the Court’s reasoning was that the hospitalization benefit at issue under the pre-ACA version of the Medicaid Act did not guarantee a level of benefits that amounted to “adequate health care.”²⁹

In 2010, the Affordable Care Act changed the standard—not just for Medicaid, but for virtually all health insurance plans. The ACA ushered in a new era for health care equity—implementing sweeping reforms to expand health coverage; creating explicit protections in enrollment, cost-sharing, and benefit design; and improving the scope and quality of health insurance. As an integral component of these reforms, Congress

²⁸ *Id.* at 302, 308.

²⁹ *Id.* at 303.

mandated comprehensive health benefit coverage and explicitly prohibited discriminatory practices in the *content* of those plans. First, it required all plans offered in the individual and small group markets to provide ten categories of essential health benefits (“EHBs”) and the items and services within those categories.³⁰ Critically, it directed that the “benefit design” of those plans must not “discriminate against individuals because of their age, disability, or expected length of life.”³¹ Second, through Section 1557, it established a health care-specific civil rights law.³² Section 1557 applies to *all* health plans that accept federal financial assistance³³ and, as a part of its carefully crafted framework, it expressly prohibits insurers from designing plan benefits and employing marketing practices that discourage people with disabilities from enrolling.³⁴ Finally, the ACA significantly expanded administrative oversight of health plans, alleviating concerns that a court-imposed remedy would mandate an “unworkable” burden. It implemented a comprehensive, multi-prong approach to monitoring and enforcing its benefit design requirements, established private enforcement mechanisms through Section 1557, and

³⁰ 42 U.S.C. § 18022. The ACA directs the HHS Secretary to further define the EHBs and, in doing so, “take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups” and “ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals’ age or expected length of life or of the individuals’ present or predicted disability, degree of medical dependency, or quality of life,” among other considerations. *Id.* § 18022(b)(4).

³¹ 42 U.S.C. § 18022(b)(4)(B); *see also* 45 C.F.R. §§ 156.110(d), 156.125 (prohibiting benefit designs that discriminate on the basis of “present or predicted disability, degree of medical dependency, quality of life, or other health conditions”).

³² *See* 42 U.S.C. § 18116(a).

³³ Federal financial assistance includes the tax credits and subsidies that private health insurers receive from State and Federal health care exchanges. *See* 45 C.F.R. §§ 92.3–.4.

³⁴ 42 U.S.C. § 18022(b)(4)(B)

created a comprehensive review system for state and federal agencies to check and enforce compliance with the ACA's EHB, cost-sharing, network adequacy, and nondiscrimination requirements.³⁵

Notably, the ACA also explicitly indicated the impermissibility of the QALY in contexts in which comparative effectiveness research was considered, prohibiting the use of the QALY in Medicare and the law's Patient-Centered Outcomes Research Institute.³⁶

Just like the Supreme Court carefully scrutinized the terms and intent of the pre-ACA Medicaid Act in *Choate*, any court evaluating a discriminatory health care practice must now take into account the ACA's robust reforms to the U.S. health care system. Private insurers are now constrained by law to offer non-discriminatory benefit packages, to which applicants and members must have "meaningful access" under disability nondiscrimination law. While the ACA does not require health care entities to cover all treatments for all people at a minimal cost to the individual, it does require access to

³⁵ *Id.* § 18031(c), (d). Plans designs that, for example, have a discriminatory impact on disabled insureds, can now be decertified and removed from the exchange until they come into compliance. *Id.* § 18031(d)(4)(A).

³⁶ In addition, HHS CMS has explicitly indicated that value-based purchasing arrangements are subject to federal non-discrimination law. In a December 31, 2020 rulemaking the department indicated that "in accordance with legal obligations under section 504 of the Rehabilitation Act, the Americans with Disabilities Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act, manufacturers and payers, including state Medicaid agencies, may not make use of measures that would unlawfully discriminate on the basis of disability or age when designing or participating in VBP arrangements." HHS CMS, *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements*, 85 Fed. Reg. 87000 (Dec. 31, 2020), available at <https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>.

affordable coverage, prohibits arbitrary denials of service, and requires that benefit plans not be structured in a way that discriminates against people with disabilities.³⁷

1. Post-ACA Disability Discrimination Claims: Disparate Treatment and “Proxy” Discrimination

In *Schmitt v. Kaiser Foundation Health Plan*, the U.S. Court of Appeals for the Ninth Circuit confirmed the ACA’s significant impact on health care nondiscrimination law—making clear that the design of a health care benefits package cannot discriminate against people with disabilities.³⁸ In *Schmitt*, the Ninth Circuit considered whether a private health insurance plan that excluded nearly all treatment for hearing loss facially discriminated against people with hearing disabilities.³⁹ The plaintiffs argued that, because the plan excluded all hearing loss treatment (except for state-mandated cochlear implants), it categorically discriminated against people with hearing disabilities, and therefore constituted “proxy” discrimination in violation of the ACA’s nondiscrimination provision.⁴⁰ Citing the ACA’s significant reforms to the U.S. health care system, the Ninth Circuit held: “While [the ACA] does not guarantee individually tailored health care plans, it attempts to provide *adequate health care* to as many individuals as possible by requiring insurers to provide essential health benefits. And it imposes an affirmative obligation not to discriminate in the provision of health care—in particular, to *consider the needs of disabled people and not design plan benefits in ways that discriminate against them.*”⁴¹

³⁷ See *id.* §§ 300gg-6, 18022.

³⁸ No. 18-35846, 2020 U.S. App. LEXIS 21902, at **18-26 (9th Cir., July 14, 2020).

³⁹ *Id.* at *4.

⁴⁰ *Id.* at **4–5, 26–27.

⁴¹ *Id.* at **17–18 (emphasis added).

Ultimately, the *Schmitt* court found that complaint’s allegations regarding the exclusion of hearing loss treatments did not state a claim for facial or “proxy” discrimination, given the exclusion’s application to people with non-disabling hearing loss and people without hearing loss who merely required a screening.⁴² The court noted the absence of certain allegations that could support plaintiffs’ claim of unlawful disability discrimination, including that the exclusion functions to “overdiscriminate” against persons with hearing disabilities, that it primarily affects disabled persons, or that the inclusion of cochlear implants does not serve most people with hearing disabilities.⁴³ Given that such additional allegations could form the basis of a valid discrimination claim under Section 1557, the court affirmed dismissal, but reversed the district court’s decision not to allow amendment, and remanded with instructions to do so.

In support of its arguments, the Epstein Becker Report cites a decision that has now been overturned by the U.S. Court of Appeals for the Ninth Circuit: *Doe One v. CVS Pharmacy, Inc.*, 348 F. Supp. 3d 967 (N.D. Cal. 2018). In *CVS Pharmacy*, the U.S. District Court for the Northern District of California considered, but ultimately rejected a claim of discriminatory benefit design in a health plan policy that required beneficiaries with HIV/AIDS to obtain their HIV/AIDS medication either via mail order or through drop shipment to a CVS pharmacy. The lower court rejected the claim, in part on grounds that the claim did not rise to a denial of meaningful access within the meaning of *Choate*. On appeal, the Ninth Circuit reversed that decision, holding that that a discriminatory benefit design includes not only facially discriminatory policies, but also those that have a

⁴² *Id.* at **23–27.

⁴³ *Id.* at **26-30.

“disparate impact” on people with disabilities, such as to “den[y] meaningful access to an ACA-provided benefit.” 982 F.3d 1204, 1211–12 (9th Cir. 2020), *cert. granted*. Following the reasoning in *Alexander v. Choate*, 469 U.S. 297, 303–06 (1985), the Ninth Circuit also affirmed that a “meaningful access” claim must be evaluated in relation to the purposes of the statute that establishes the benefit, including those guaranteed by the ACA. *Id.* at 1211.⁴⁴

Here, a covered entity’s use of the QALY in determining whether to cover a certain drug or treatment (or, if they are covered, at what cost, under what terms, and with what level of cost sharing) could result in a denial of meaningful access to health care benefits within the meaning of *Choate* and *Schmitt*. While the success of any disability nondiscrimination claim will be fact-specific, a public or private health care plan’s use of

⁴⁴ One circuit court case, not cited by the Epstein Becker Report, contradicts *Schmitt*. In *Doe v. BlueCross BlueShield of Tennessee*, No. 18-5897, 2019 U.S. App. LEXIS 16785 (6th Cir. June 4, 2019), the Sixth Circuit rejected the actionability of discriminatory benefit design claims under Section 1557 of the ACA and, in dicta, also posited that disparate impact discrimination is not actionable under Section 504. *See id.* at *13. This decision is in contradiction of the U.S. Supreme Court’s holding in *Choate*, ignoring the ACA’s purposes and the statutory context for Section 1557, even though the *Choate* Court was careful to evaluate the challenged policy against the purpose and history of the underlying statute. *See id.* This repudiation of *Choate* and other Section 504 case precedent (such as *CONRAIL v. Darrone*, 465 U.S. 624 (1984) (cited by *Choate*, 469 U.S. at 295) (holding that Section 504 does not incorporate Title VI’s substantive limitations on actionable discrimination) is contrary to the purposes, letter, and spirit of the law and its long-standing regulations. Further, even if the policy at issue in *BlueCross BlueShield* did not rise to the level of a denial of meaningful access, it can be factually distinguished from the use of QALYs. In *BlueCross BlueShield*, like in *CVS Pharmacy*, the challenged policy required HIV/AIDS medication to be obtained via mail order or drop shipment. Here, use of the QALY can function to completely block coverage of the medication that people with certain disabilities need to function or live longer lives. The latter imposes a graver impact on people with disabilities and relies on biased data sources. As such, it forms a stronger basis for a disability discrimination claim.

the QALY—a measure that, as previously detailed, inherently relies on biased notions of life with a disability—holds a high risk of judging the pharmaceuticals that people with disabilities uniquely rely on to be of a lower projected “value” than pharmaceuticals primarily utilized by people without disabilities. Such a result would run straight into a scenario contemplated by the *Choate* Court itself—by preventing conditions “uniquely associated with the handicapped or occurring with greater frequency among them” from being “effectively treated, at least in part.”⁴⁵ Moreover, reliance on QALY measures would likely run afoul of the precedent set in *Schmitt*, by failing to “consider the needs of disabled people and not design plan benefits in ways that discriminate against them.”⁴⁶ The exclusion of treatments disproportionately relied upon by people with disabilities, because of a measure that systemically and inaccurately devalues their lives, fails to equally take into account the needs of people with disabilities. As such, it poses a high risk of constituting a discriminatory benefit design.

2. Post-ACA Disability Discrimination Claims: Disparate Impact and “Screen Out” Discrimination

In addition to the categorical or “proxy” exclusions challenged in *Schmitt*, “meaningful access” to a health care benefit can be denied when a policy disproportionately burdens disabled people, so as to effectively reduce their access to services, programs, or activities that are accessible to others.⁴⁷ Following *Choate*, a

⁴⁵ *Choate*, 469 U.S. at 302 n.22.

⁴⁶ *Schmitt*, 2020 U.S. App. LEXIS 21902, at **17–18 (emphasis added).

⁴⁷ See, e.g., *Rodde v. Bonta*, 357 F.3d 988, 997–98 (9th Cir. 2004); *Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996); *Prewitt v. U.S. Postal Serv.*, 662 F.2d 292, 306 (5th Cir. 1981); *NAACP v. Med. Ctr., Inc.*, 657 F.2d 1322, 1331 (3d Cir. 1981) (en banc).

series of decisions in U.S. Courts of Appeals defined the contours of when a disproportionate effect of a policy rises to the level of denial of meaningful access.

For example, in *Crowder v. Kitagawa*, the Ninth Circuit evaluated whether Hawaii's animal quarantine rule, neutral on its face, had a discriminatory effect on visually-impaired people who relied on guide dogs.⁴⁸ The rule mandated a 120-day quarantine for all carnivorous animals entering the State, in an effort to prevent the spread of rabies.⁴⁹ The State sequestered all guide dogs under the rule, though it did provide housing accommodations for their disabled owners and permitted the dogs to train with them.⁵⁰ The Ninth Circuit, citing *Choate*, held that the quarantine rule denied visually-impaired people "meaningful access" to public services.⁵¹ It explained:

Although Hawaii's quarantine requirement applies equally to all persons entering the state with a dog, its enforcement burdens visually-impaired persons in a manner different and greater than it burdens others. Because of the unique dependence upon guide dogs among many of the visually-impaired, Hawaii's quarantine effectively denies these persons . . . meaningful access to state services, programs, and activities while such services, programs, and activities remain open and easily accessible by others.⁵²

In its analysis, the court emphasized how the rule "effectively preclude[d]" people with visual impairments from using public services and participating in their communities.⁵³ For example, without their guide dogs, people were unable to use public transit, enjoy parks, and navigate streets and buildings.⁵⁴ Notably, the court's analysis focused on how

⁴⁸ 81 F.3d at 1481–83.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 1484–85.

⁵² *Id.* at 1484.

⁵³ *Id.* at 1485.

⁵⁴ *Id.*

a policy of one type (the movement of animals into the State) can have a discriminatory effect on the accessibility of *other* services, programs, and activities (e.g., transportation and building accessibility). This concept, as courts have subsequently recognized,⁵⁵ transcends the context of transportation and applies equally to health provider and/or insurer policies that, in effect, limit or inhibit people with disabilities from functioning independently and participating in their communities.

Likewise, in *Rodde v. Bonta*, the Ninth Circuit considered whether a county's decision to close a medical facility that disproportionately provided services to disabled people constituted a denial of "meaningful access."⁵⁶ The facility was the only one in the county that provided specialized rehabilitative services primarily (but not exclusively) to disabled people.⁵⁷ The court, citing *Choate* and *Crowder*, held that the county's plan denied meaningful access to health care services.⁵⁸ It explained:

Eliminating entirely the only hospital of six that focuses on the needs of disabled individuals . . . and that provides services disproportionately required by the disabled and available nowhere else in the County is simply *not* the sort of facially neutral reduction considered in *Alexander*. *Alexander* may allow the County to step down services equally for *all* who rely on it for their health-care needs, but it does not sanction the wholesale elimination of services relied upon disproportionately by the disabled because of their disabilities.⁵⁹

⁵⁵ See, e.g., *Rodde*, 357 F.3d at 997–98; *Schmitt*, 2020 U.S. App. LEXIS 21902, at **18–19.

⁵⁶ 357 F.3d at 997–98.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* at 997 (emphasis in original).

The closure of the facility “would deny certain disabled individuals meaningful access to government-provided services because of their unique needs,” it concluded.⁶⁰ Thus, it would constitute disability discrimination within the meaning of *Choate*.⁶¹

Other U.S. Courts of Appeal have also found denials of meaningful access when disabled people are disadvantaged or denied services that they uniquely rely on by a health care programs and activities. For example, in *Helen L. v. DiDario*, the U.S. Court of Appeals for the Third Circuit held that a Pennsylvania Medicaid program that denied attendant care services to people with disabilities due to lack of adequate funding, forcing them into nursing homes, constituted a denial of meaningful access to such services within the meaning of *Choate*.⁶² Additionally, in *Henrietta D. v. Bloomberg*, the U.S. Court of Appeals for the Second Circuit held that the city of New York’s consolidation of all health care services for HIV-positive patients into a single agency, which proved to be dysfunctional, denied people with HIV meaningful access to healthcare benefits.⁶³ Notably, the Second Circuit denied the city defendant’s request to introduce comparative evidence showing that people without disabilities faced similar difficulties accessing social services, finding the failure to provide adequate healthcare so egregious that comparative evidence was unnecessary.⁶⁴

Here, should a health care plan rely on the QALY in its pharmaceutical decisionmaking, it would likely have a disproportionate impact on people with disabilities

⁶⁰ *Id.* at 998.

⁶¹ *Id.*

⁶² 46 F.3d 325, 335 (3d Cir. 1995) (cited favorably by the U.S. Supreme Court in *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581 (1999)).

⁶³ 331 F.3d 261, 269 (2d Cir. 2003).

⁶⁴ *Id.* at 283 n.11.

within the meaning of *Crowder, Rodde, Helen L., and Henrietta D.* As an example, consider the coverage of pharmaceuticals used to treat opioid use disorder (“OUD”), a condition characterized by the overpowering desire to use opioids, increased opioid tolerance, and withdrawal syndrome when use is discontinued—all of which lead to clinically significant impairment or distress.⁶⁵ The FDA has approved three medications for the treatment of OUD: methadone, buprenorphine, and naltrexone.⁶⁶ All of these drugs extend life by reducing fatal overdoses and reduce rates of disease transmission.⁶⁷ Based on surveys of people with OUD, these drugs also significantly increase their daily functioning and improve their quality of life across physical, psychological, social, and environmental domains.⁶⁸ However, external evaluations of the quality of life of a person with OUD are markedly lower—that is, physicians, healthcare professionals (e.g., personal assistants), and the general public undervalue, stigmatize, and hold negative attitudes about life with this disease and the medications used to treat it.⁶⁹ By relying on

⁶⁵ CDC, *Assessing and Addressing Opioid Use Disorder (OUD)*, <https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html> (last visited July 23, 2021).

⁶⁶ INST. FOR CLINICAL & ECONOMIC REVIEW, *Extended-Release Opioid Agonists and Antagonist Medications for Addiction Treatment (MAT) in Patients with Opioid Use Disorder: Effectiveness and Value* (December 3, 2018), *available at* https://icer.org/wp-content/uploads/2020/10/ICER_OUD_Final_Evidence_Report_120318.pdf.

⁶⁷ *Id.*

⁶⁸ See e.g., Kobra Lashkaripour, et al., *Quality of life in patients on methadone maintenance treatment: a three-month assessment*, 62 J. PAK. MED. ASSOC., no. 10, 1003–07 (Oct. 2012); Ying-Chun Chou, et al., *Improvement of quality of life in methadone treatment patients in northern Taiwan: a follow-up study*, 13 BMC PSYCHIATRY, no. 190 (July 16, 2013).

⁶⁹ See, e.g., Stella Resko, et al., *Public Perception of the Efficacy of Medications for Opioid Addiction Treatment*, Society for Social Work and Research (Jan. 17, 2020), <https://sswr.confex.com/sswr/2020/webprogram/Paper37269.html>; Steven Ross Johnson, *Public perception is tough to overcome in battle against opioid addiction*,

the QALY in this situation, the life extension value for the three drugs for OUD treatment would be discounted because of these negative perceptions—meaning that a health care plan may then erroneously determine such medications are not worth the cost to cover, or if they are covered, that they should be placed in a high-cost drug tier. In this example, people with OUD will face a disproportionately negative impact from the plan’s reliance on the QALY. Without the drugs they need to improve their daily functioning, then the person with this disability may be “effectively precluded” from “participating in their communities,” like in *Crowder*⁷⁰ and *Helen L.*⁷¹ Or, it could cause a health plan to eliminate or severely reduce the availability of “services disproportionately required by” people with certain disabilities “and available nowhere else,” like in *Rodde*⁷² and *Henrietta D.*⁷³ While the coverage of treatments used to treat OUD disease is just one example, it is easy to see how a health care payer’s reliance on an inherently biased measure could have a devastating impact on the health care coverage of essential services relied upon by people with all sorts of disabilities. Such a result is simply “*not* the sort of facially neutral reduction considered in *Alexander*,”⁷⁴ nor is it what Congress intended in enacting the

Modern Healthcare (May 26, 2018), <https://www.modernhealthcare.com/article/20180526/NEWS/180529957/public-perception-is-tough-to-overcome-in-battle-against-opioid-addiction>; Alene Kennedy-Hendricks, et al., *Social Stigma Toward Persons With Prescription Opioid Use Disorder: Associations With Public Support for Punitive and Public Health–Oriented Policies*, 68 *Psychiatric Srvcs.*, no. 5, 462–69 (May 2017), available at <https://ps.psychiatryonline.org/doi/pdf/10.1176/appi.ps.201600056>.

⁷⁰ See 81 F.3d at 1485.

⁷¹ See 46 F.3d at 335.

⁷² See 357 F.3d at 997–98.

⁷³ 331 F.3d at 269.

⁷⁴ *Rodde*, 357 F.3d at 997–98.

ADA, Section 504, and their predecessor in the health-specific context: Section 1557 of the ACA.

B. Case Precedent Involving Long-Term Disability Insurance Should Not Be Applied to the Context of ACA-Governed Health Care.

The Epstein Becker Report attempts to rely on *Parker v. Metropolitan Life Insurance Company*⁷⁵ and *E.E.O.C. v. Staten Island Savings Bank*,⁷⁶ both cases involving distinctions between people with mental versus physical disabilities in long-term disability insurance, for the proposition that discriminatory health care benefit designs are not actionable. *Parker* and *E.E.O.C.* are not controlling on the QALY analysis, as both cases involve long-term disability insurance and not health care benefits. Generally, long-term disability insurance provides a daily cash benefit intended to replace a beneficiary's employment income upon encountering an illness or injury that prevents work. Long-term disability insurance is *income* insurance, not health insurance. The income and health insurance markets are distinct industries; they are subject to different federal laws, can be regulated by different entities, and are characterized by disparate purposes, market structures, and industry norms.⁷⁷ Long-term disability insurance is not governed by the ACA, a healthcare and health insurance-specific statute passed after both cases were decided. Case precedent dictating permissible policies in the distinct context of long-term disability insurance is inapplicable to this context.

⁷⁵ 121 F. 3d 1006 (6th Cir. 1997).

⁷⁶ 207 F.3d 144 (2d Cir. 2000).

⁷⁷ See Timothy Jost, *Implementing Health Reform: Excepted Benefits Final Rule*, *HealthAffairs* (Sept. 29, 2014), <https://www.healthaffairs.org/doi/10.1377/hblog20140929.041684/full/>.

Conclusion

Public and private health care entities need some measure by which to determine which drugs and therapies are feasible and “worth it” to cover, and which are not. However, such measures cannot be based on discriminatory assumptions about the quality of life with a disability, nor can reliance on the measure produce a disproportionately negative impact on the health care services and treatments that people with disabilities uniquely rely on. The QALY does both and, for this reason, runs afoul of disability nondiscrimination law and should not be utilized by health care decisionmakers. The lives of all individuals—regardless of disability—are equally valuable; this fundamental principle cannot be ignored for the sake of cost savings.

Instead of relying on the QALY, or attempting to “fix” it with the equally flawed evLYG measure, payers should make use of a variety of emerging alternatives to the QALY. For example, the recently proposed Health Years in Total (“HYT”) framework is similar to the QALY, but with one critical distinction: it separates out the evaluations of life extension and quality of life improvement, and only uses utility values to discount the latter (as opposed to the QALY, which discounts both).⁷⁸ The advantage of this approach is that it removes one discriminatory component from the QALY: the undervaluing of life extension of a person with a disability.⁷⁹ The HYT still relies on broader societal preferences for determining how to value quality of life improvements through the same utility weights the QALY relies on, representing a problematic aspect of the methodology. While not undervaluing life-extension under an HYT framework, these weights still fail to

⁷⁸ Anirban Basu, et al., *Health Years in Total: A New Health Objective Function for Cost-Effectiveness Analysis*, 23 VALUE HEALTH, no. 1, 96–103, 97–98 (2020).

⁷⁹ *Id.* at 96–97.

account for the complexity of disabled living compared to condition-specific measures, which can evaluate symptoms and QoL with much greater nuance and precision. They also still reflect society's judgments about disabled life rather than those of people with disabilities themselves.

However, the HYT still represents a distinct improvement over the QALY by virtue of eliminating the undervaluation of life-extension. Distributionally, the HYT would likely elevate the relative priority given to interventions that extend the lives of those with chronic conditions without providing a full cure. Because the HYT uses the same weights the QALY does, any value assessment done using the QALY can easily be replicated using the HYT without new data collection, easing adoption.

Another potential alternative may be found by giving up on the idea of comparability across all patient populations in favor of alternative measure(s) that make use of condition specific measures. For example, the Efficiency Frontier ("EF") method benchmarks the price of a new drug to the value of existing drugs, relying on the particular outcome(s) that the existing drugs have on a given condition in order to calculate a cost per outcome unit, which is then used to calculate the recommended cost of the new drug.⁸⁰ The advantage of the EF is that it eliminates the QALY-based utility values that can rely on discriminatory assumptions, in favor of multiple condition-specific measures.⁸¹ However, the EF too has its challenges: it does not allow for comparisons across

⁸⁰ Axel C. Mühlbacher & Andrew Sadler, *The Probabilistic Efficiency Frontier: A Framework for Cost-Effectiveness Analysis in Germany Put into Practice for Hepatitis C Treatment Options*, 20 HEALTH 266–72, 267 (2017).

⁸¹ *Id.* at 267–68.

conditions. Additionally, by relying on existing benchmark drugs, a new drug may be over- or under-valued depending on recent pharmaceutical innovation, or the lack thereof.

There is no perfect solution to pharmaceutical pricing. However, there are alternative metrics in development that, when used jointly, can reduce reliance on discriminatory assumptions about people with disabilities and improve access to life-sustaining or life-improving treatments. The abandonment of the QALY in favor of non-discriminatory alternatives that consider the diverse needs of people with disabilities is a vital first step toward equity in pharmaceutical decisionmaking.