Center for Community Inclusion
& Disability Studies
Maine's University Center for Excellence in Developmental Disabilities Education, Research and Service (UCEDD)

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February 15, 2022

Re: Testimony **Neither For Nor Against LD 1636**, "An Act To Reduce Prescription Drug Costs by Using International Pricing"

Chairwoman Sanborn, Chairwoman Tepler, Distinguished Members of the Joint Standing Committee on Health Coverage, Insurance and Financial Services:

My name is Alan Cobo-Lewis. I live in Orono. I am director of the Center for Community Inclusion and Disability Studies (CCIDS) at the University of Maine.

CCIDS is Maine's federally funded University Center for Excellence in Developmental Disabilities (UCEDD, pronounced "YOU-said", authorized by the federal Developmental Disabilities Assistance and Bill of Rights Act of 2000 ("DD Act"). The purpose of the national network of UCEDDs is to provide leadership in, advise federal state and community policy leaders about, and promote opportunities for individuals with developmental disabilities to exercise self-determination, be independent, be productive, and be integrated and included in all facets of community life. Part of the federal mandate of CCIDS is to educate and advise policymakers, including members of the state legislature. Consistent with CCIDS responsibilities under the DD Act and consistent with University of Maine Board of Trustees policies 212 and 214, I am testifying on the bill for myself and for CCIDS, not for the University of Maine or the University of Maine System as a whole.

1 Summary of the Bill

LD 1636, as introduced, would mandate the following:

- The executive director of health insurance at DAFS would annually list the 250 most costly prescription drugs based on net price times utilization.
- Referenced rates for these drugs would be determined as the lowest cost among wholesale acquisition cost and official publications of Ontario, Quebec, British Columbia, and Alberta, with the list of referenced drugs also determined on analysis of cost savings from subjecting drugs to referenced rates.
- State health insurance plans, and any ERISA plan that opts to participate, would be prohibited from paying more than the referenced rate for these drugs.
- A manufacturer or distributor of a referenced drugs would be prohibited from withdrawing that drug from sale or distribution in Maine in order to avoid the rate limitations.

2 QALYs and Potential Discrimination Against People with Disabilities

Ontario, Quebec, British Columbia, and Alberta are all referenced explicitly in the bill, and all use Quality Adjusted Life Years (QALYs) in determining pricing. Using QALYs in determining a ***formulary*** is potentially problematic, because using QALYs in this manner can have a discriminatory impact against people with disabilities. Because LD 1636 may indirectly use QALYs in determining ***pricing***, there is less potential for

discrimination, but the potential may still exist, especially where price controls may affect access. However, there are solutions. This is especially important, since high prices themselves can also present a barrier to access.

2.1 QALYs and States Deemed "Worse than Death"

QALYs weight the lives of people with disabilities less than the lives of people without disabilities. In the health utility that feeds a QALY calculation, a year of life for a young and perfectly healthy person is valued at 1 QALY, a year of life for a person with total blindness could be valued at 0.26 (about one-quarter of the value of a year of life for a young and healthy person)[1], and a year of life for a young child with Type 1 spinal muscular atrophy, as assessed using weighting from the general population, might be valued at only −0.12 QALY[2]—less than zero, deeming the child to be in a state worse than death! As a consequence, a drug that extends the life of a child with Type 1 spinal muscular atrophy while having neither positive nor negative effect on their quality of life would be deemed to have negative value—too expensive at any price! Using QALYs to assess a drug's life-extension effect is clearly discriminatory against persons with disabilities.

2.2 QALYs May Not Use Data Collected from Relevant Patient Population

The health utilities that feed QALYs frequently come from surveys of the general population about what they ***think*** their quality of life would be if they had various conditions (e.g., the EQ-5D-5L value set for England[3], Canada[4], or Japan[5]; the 36-item short form survey [SF-36][6]). In one study of an EQ-5D dataset, it was found that if even 15% of respondents deemed a condition as worse than death, the mean life value across the entire sample became negative.[7] And yet, in a study that surveyed people ranging in age from 65 to 102, 1.8% of whom (115 of respondents) were deemed by the EQ-5D UK dataset to be in states worth than death, 45% judged themselves to be "happy" or "fairly happy", and about one-third reported being "quite satisfied" to "very satisfied" with their life.[8] It is critical, therefore, that the health

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[1] Brown, M. M., Brown, G. C., Sharma, S., Kistler, J., & Brown, H. (2001). Utility values associated with blindness in an adult population. *British Journal of Ophthalmology, 85,* 327-331. https://doi.org/10.1136/bjo.85.3.327

[2] Lloyd, A. J., Thompson, R., Gallop, K., & Teynor, M. (2019). Estimation of the quality of life benefits associated with treatment for spinal muscular atrophy. *ClinicoEconomics and Outcomes Research, 11,* 615-622. https://doi.org/10.2147/CEOR.S214084

[3] Devlin, N. J., Shah, K. K., Feng, Y., Mulhern, B., & van Hout, B. (2016). Valuing health-related quality of life: An EQ-5D-5L value set for England. *Health Economics, 2017,* 1-16. https://doi.org/10.1002/hec.3564

[4] Xie, F., Pullenayegum, E., Gaebel, K., Bansback, N., Bryan, S., Ohinmaa, A., Poissant, K., & Johnso, J. A. (2016). A time trade-off derived value set of the EQ-5D-5L for Canada. Medical Care, 54(1), 98-105. https://doi.org/10.1097/MLR.0000000000000447

[5] Shiroiwa, T., Ikeda, S., Noto, S., Igarashi, A.,. Fukuda, T., Saito, S., & Shimozuma, K. (2016). Comparison of value set based on DCE and/or TTO data: Scoring for EQ-5D-5L health states in Japan. *Value in Health, 19(5),* 648-654. https://doi.org/10.1016/j.jval.2016.03.1834

[6] Hays, R. D., Sherbourne, C. D. & Mazel, R. M. (1995). User's manual for the medical outcomes study (MOS) core measures of health-related quality of life. Santa Monica, CA: Rand Corporation. https://www.rand.org/pubs/monograph_reports/MR162.html

[7] Lamers, L. M. (2007). The transformation of utilities for health states worse than death: Consequences for the estimation of EQ-5D value sets. *Medical Care, 45(3),* 238-244. https://www.jstor.org/stable/40221407

[8] Bernfort, L., Gerdle, B., Husberg, M., & Levin, L.-Å. (2018). People in states worse than dead according to the EQ-5D UK value set: would they rather be dead? *Quality of Life Research, 27,* 1827-1833. https://doi.org/10.1007/s11136-018-1848-x

utilities feeding a QALY calculation be validated with the specific patient population whose benefit from the drug is to be estimated.

2.3 QALYs using EQ-5D may Not Be Fit for Some Mental Health and Disabling Conditions

There is some evidence supporting the validity of EQ-5D for some mental health conditions, but less evidence supporting its validity for other mental health conditions[9]. The EQ-5D itself may also not be sufficiently validated for vision problems, though there is a "vision bolt-on" that could improve validity for this purpose[10]. The validity of the EQ-5D-Y (a version of the EQ-5D for youth) in children and young people with cerebral palsy is currently unclear[11]. There is, on the other hand, some evidence that the EQ-5D may have validity for patients with dementia (regardless of whether completed by patients or proxies) and might even have some advantages over some dementia-specific measures[12]. On the other hand, the EQ-5D-3L appears to have weak validity for adults with mild to moderate intellectual disability[13].

2.4 Potential Violation of Rehabilitation Act, ADA, and ACA

A report recently commissioned by the Institute for Clinical and Economic Review (ICER) has concluded the QALYs pose no risk of discrimination against any patient group[14], but the Disability Rights Education and Defense Fund strongly disagrees[15], seeing QALYs as violations of the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the Affordable Care Act.

3 Alternatives to QALYs

There are alternatives to QALYs. For example, Equal Value of Life Years Gained (evLYG) does not apply the problematic discounting when calculating effect of a drug on life extension. This explains why ICER

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[9] Brazier, J. (2018). Is the EQ-5D fit for purpose in mental health? *British Journal of Psychiatry, 197(5),* 348-349. https://doi.org/10.1192/bjp.bp.110.082453

[10] Luo, N., Wang, X., Ang, M., Finkelstein, E. A., Aung, T., Wong, T.-Y., & Lamoureux, E. (2015). A vision "bolt-on" item could increase the discriminatory power of the EQ-5D index score. *Value in Health, 18(8),*1037-1042. https://doi.org/10.1016/j.jval.2015.08.002

[11] Ryan, J. M., McKay, E., Anokye, N., Noorkoiv, M., Theis, N., & Lavelle, G. (2020). Comparison of the CHU-9D and the EQ-5D-Y instruments in children and young people with cerebral palsy: a cross-sectional study. *BMJ Open, 10,* e037089. https://doi.org/10.1136/bmjopen-2020-037089

[12] Aguirre, E. Kang, S., Hoare, Z., Tudor Edwards, R., & Orrell, M. (2016). How does the EQ-5D perform when measuring quality of life in dementia against two other dementia-specific outcome measures? *Quality of Life Research, 25,* 45-49. https://doi.org/10.1007/s11136-015-1065-9

[13] Russell, A. M., O'Dwyer, J. L., Bryant, L. D., House, A. O., Birtwistle, J. C. Meer, S., …, Hulme, C. T. (2018). The feasibility of using the EQ-5D-3L with adults with mild to moderate learning disabilities within a randomized control trial: a qualitative evaluation. *Pilot and Feasibility Studies, 4,* 164. https://doi.org/10.1186/s40814-018-0357-6

[14] Morris, F. C., Gabay, A., & Epstein Becker & Green, P.C. (2021). ICER analyses and payer use of cost-effectiveness results based on the QALY and evLYG are consistent with ADA protections for individuals with disabilities. Retrieved February 12, 2022, from https://icer.org/wp-content/uploads/2021/02/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

[15] Disability Rights Education and Defense Fund (2021). Pharmaceutical analyses based on the QALY violate disability nondiscrimination law. Retrieved February 12, 2022, from https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law

has recently added evLYG to its analyses[16]. This is an important change. However, exclusive use of evLYG would fail to account for genuine and important improvements in quality of life, which is why ICER currently uses evLYGs and QALYs together (evLYG to assess effectiveness at life extension, QALY to assess effectiveness at improving health-related quality of life). But this does not address the problem of QALYs being fed by health utility measures when they have not been validated in the relevant patient population.

There are additional alternatives, reviewed in plain language in Chapter 5 of a 2019 report by the National Council on Disability[17], which is an independent federal agency that advises the executive and congressional branches, as well as state, tribal, local governments and other entities and organizations, regarding policies, programs, practices, and procedures that affect people with disabilities.

4 Potential Language to Address the Issue

The Committee might consider an amendment to proposed 22 MRS §2688(4)(E) on lines 28-33 on page of LD 1636 to address the potential for discrimination against people with disabilities and the potential for lack of mental health parity (adapted from language on page 2 lines 34-39 of adopted Committee Amendment "B" to LD 675):

> E. The determination by the Superintendent of Insurance of which prescription drugs to include on the list of referenced drugs must be based upon an analysis of the saving that could be achieved by subjecting those prescription drugs to the referenced rate. In making this determination, the Superintendent of Insurance shall consult with the Executive Director of Health Insurance and the president of the Maine Board of Pharmacy. In making this determination, the Superintendent of Insurance, in consultation with the Maine Prescription Drug Affordability Board, must also ensure that the determination does not discriminate against persons with disabilities.

Very Truly Yours,

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Associate Professor of Psychology

[16] Institute for Clinical and Economic Review (n.d.). Cost-effectiveness, the QALY, and the evLYG. Retrieved February 12, 2022, from https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/

[17] National Council on Disability (2019, November 6). Quality-adjusted life years and the devaluation of life with disability. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf