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H.R. 3's international reference pricing misses the mark

By Susan Peschin *and* Duane Schulthess April 28, 2021

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The White House and Congress have declared that reining in Medicare prescription drug costs to help older adults and people with disabilities is a top priority. But one drug pricing strategy on the table would have an outsized negative impact on people with Alzheimer's disease and decimate research trying to find effective treatments for it.

This strategy, known as international reference pricing, ties the price that Medicare pays for some drugs to those paid by other countries. The idea was first introduced as a model for Medicare Part B drugs by then-HHS Secretary Alex Azar in 2018. The next year, House Speaker Nancy Pelosi's drug pricing plan, known as the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3),

significantly expanded the scope to allow federal government use of foreign price controls in direct negotiations with pharmaceutical companies for the cost of 250 prescription medicines in Medicare Part B and Part D. It also extended the negotiated price to insurers and the commercial market at large.

Not to be outdone, the Trump administration took another swing at international reference pricing with its "most favored nations" executive order that promised to lower drug prices even further.

Recently reintroduced, H.R. 3 may be voted on in the House of Representatives as early as May.

All international reference pricing proposals share a common flaw: They import to the United States the use of discriminatory cost-effectiveness standards that other governments use. Many of the referenced countries, such as the United Kingdom, Canada, and Greece, make drug reimbursement and coverage decisions based on cost-effectiveness assessments tied to the quality-adjusted life year (QALY).

QALY assessments assign a value to the patient population a treatment is intended for. These assessments are based on the perceived value of living with a given condition in comparison to being in "perfect health." By definition, QALYs undervalue treatments for populations that have fewer expected years of life left or shorter life spans than the overall population. In short, if a therapeutic treats a condition for a group that is sicker, older, or includes people with disabilities, or is focused on a population that has historically faced inequities in society and in the health care system, the treatment is assessed as being less valuable. By concluding that a treatment is not cost-effective, payers can justify restricting access by not covering it or using management techniques that effectively restrict access to it.

In 2019, the National Council on Disability (NCD), an independent federal agency, cautioned against relying on the QALY because it would undermine the Affordable Care Act and major U.S. disability and civil rights laws,

including the Rehabilitation Act and the Americans with Disabilities Act. Earlier this month, the NCD sent a letter to the Congressional Budget Office expressing its concern with the agency's use of QALYs to score H.R. 3. It stated, "This makes light of the fact that the QALY assigns a lower value to the lives of people with disabilities and chronic illnesses. It also ignores the fact that countries that rely on the QALY to set drug prices have restricted or denied patients with disabilities access to effective drugs used to treat chronic conditions and to breakthrough medications."

In 2020, the Democratic National Committee platform stated that, "Democrats will ensure that people with disabilities are never denied coverage based on the use of quality-adjusted life-year (QALY) indexes."

Given clear statements like these, we believe that policies relying on QALY-driven international pricing metrics should be prohibited, not embraced.

When applied to Alzheimer's disease and related dementias, QALY-based cost-effectiveness analyses present the ultimate moral quandary due to older age and health status. Of the 6.2 million Americans age 65 and older living with Alzheimer's, one-third are over age 75 and another one-third are over age 85, meaning Alzheimer's medicines would be expected to receive lower QALY scores. In addition, QALYs generally don't recognize the significant burden of Alzheimer's disease and other types of dementia on family caregivers and society, which means they also don't recognize the value of treatments that alleviate these burdens.

Alzheimer's disease and related dementias are a critical area of unmet medical need. The failure rate for therapies in the clinical pipeline to treat them is a staggering 98.5%. And in the ten years before H.R. 3 was introduced, 87 clinical programs investing in and researching Alzheimer's disease were closed.

Federal funding for aging and Alzheimer's research by the National Institutes of Health has gone from $448 million in 2011 to $3.1 billion in 2021. This

investment is essential and should be increased. But 70% of translational research on Alzheimer's disease and related dementias continues to be funded by pharmaceutical and biotech companies.

Given the risks of investing in medical breakthroughs for neurological conditions, companies need successful products to underwrite and subsidize the investment into new areas of this research. A new analysis by our organizations, Vital Transformation and the Alliance for Aging Research, shows that implementing international reference pricing in the U.S. would decimate the clinical development of therapies for Alzheimer's disease and related dementias and drastically reduce the revenue that helps support this critical research.

More than 30 organizations agree that Congress should keep international reference pricing proposals out of drug pricing reform legislation.

There are positive components of H.R. 3, including proposals to cap and smooth out-of-pocket costs for Medicare Part D beneficiaries. These proposals — which have received support from Democrats and Republicans alike — promote affordability and lower patient costs without restricting access to the care they need.

We share policymakers' interest in reducing health care costs. But international reference pricing misses the mark and it's time to let it go for good.

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