Alliance for Aging Research

# New Analysis Shows International Reference Drug Pricing Would Have a Catastrophic Impact on Alzheimer's Disease Research

Proposed Policy Would Likely Eliminate Future Clinical Development Programs in Alzheimer's Research, Impacting Millions of Patients and Their Families

**WASHINGTON, April 22, 2021** – The number of Americans aged 65 and older with Alzheimer´s disease (AD) is expected to more than double from 6.2 million today to 12.7 million by 2050. Currently, there are no treatments available to stop or slow the progression of the disease. At the same time, large pharmaceutical companies have already downsized investment into AD and other neurological disorders by more than 50 percent due to the associated high risk of study failure for these diseases. International reference pricing proposals (including "International Pricing Index" or "Most Favored Nation"), currently under consideration by the U.S. Congress and proposed in the previous Congress as Title I of H.R. 3, would import foreign price controls for 125 Medicare Part B and D drugs with the highest net spending based on the volume-weighted average of drug prices in Australia, Canada, France, Germany, Japan, and the United Kingdom. Previous analysis of the impact of international reference pricing (https://www.sciencexcel.com/articles/International%20Reference%20Pricing%20in%20Congressional%20Bill%20H%20R%203%20and%20 estimated a 70 percent earnings reduction in 2023 for all 125 therapies that would be potentially affected by the proposed policy.

The impact of international reference pricing is projected to have carryover adverse impacts on research funding for AD. Revenue generated from successful medical products is increasingly required to underwrite investment into high-risk AD clinical development programs. Implementing international reference pricing in the U.S. would sharply reduce the ability to cross-subsidize AD research, further diminishing already dwindling investments and progress in this disease area. This is the key takeaway of a new analysis (https://www.agingresearch.org/app/uploads/2021/04/Alzheimers-H.R.-3-Impact_FINAL.pdf) by Vital Transformation (https://vitaltransformation.com/) in collaboration with the Alliance for Aging Research (https://www.agingresearch.org).

"International reference pricing will have a catastrophic impact on people with Alzheimer's disease by decimating the clinical development of therapies for the disease and drastically reducing revenue that helps support this critical research," said Susan Peschin, MHS, President and CEO of the Alliance for Aging Research. "Alzheimer's disease is a critical area of unmet medical need, and the human cost of not finding a cure is astronomical. We share policymakers' interest in reducing costs to federal programs; however, international reference pricing misses the mark."

An Alzheimer's disease drug development program's total cost is estimated at $5.7 billion (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4285871/), with an expected study time of 13 years from preclinical studies to market approval. However, due to the clinical complexity of AD and neurological disorders, the failure rate for test therapies in the clinical pipeline to treat Alzheimer's disease is 98 percent (https://alzres.biomedcentral.com/articles/10.1186/alzrt269). Between January 2008 and February 2019, 87 out of 161 clinical programs investing and researching Alzheimer's disease closed (http://go.bio.org/rs/490-EHZ-999/images/BIO_HPCD4_ALZHEIMERS.pdf). The clinical trial success rates for AD candidates are lower than observed for all other disease areas.

According to Duane Schulthess, Vital Transformation's Managing Director, "What is particularly odd about H.R.3 as it is currently written is that it targets the most novel therapeutics simply based upon price, while obviating effectiveness. This means that even if an innovative drug offsets the costs of treatment long-term compared to standard-of-care, it has no consideration under the H.R.3 criterion. Further, the impacts of the bill are additive in that the more therapies a company develops that fall under the pricing regime, the more its total revenues are affected. Ultimately, the bill penalizes those companies that have successfully focused on producing novel in-demand drugs in areas of high unmet need."

This past decade, the federal government has dramatically increased its investment in Alzheimer's disease research, starting with $448 million in 2011 (https://www.nia.nih.gov/sites/default/files/2017-07/reaching-for-a-cure-alzheimers-disease-and-related-dementias-research-at-nih.pdf) and increasing annually to $3.1 billion in 2021 (https://www.nia.nih.gov/about/naca/january-2021-directors-status-report#:~:text=The%20FY21%20budget%20increases%20the,NIA%20through%20September%2030%2C%202021.). This investment is essential. Still, the vast amount of translational research in Alzheimer's disease continues to be funded by biotech companies. Seventy percent of all Alzheimer's disease clinical trials are sponsored or co-sponsored by pharmaceutical companies (https://www.sciencedirect.com/science/article/pii/S2352873717300379).

This analysis (https://www.agingresearch.org/app/uploads/2021/04/Alzheimers-H.R.-3-Impact_FINAL.pdf) is released in conjunction with a letter to Congressional leadership signed by over 30 patient advocacy groups, urging Congress to keep any international reference pricing proposals out of drug pricing reform legislation. In addition to the negative impact on future research, the groups expressed concern about the policy's reliance on methodologies that unintentionally discriminate against older adults, individuals with disabilities, and minority populations in violation of U.S. civil rights law. To read the letter, click here (https://www.agingresearch.org/app/uploads/2021/04/AD-International-Reference-Pricing-Letter-Sign-On-4.22.21.pdf).

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**About the Alliance for Aging Research**

The Alliance for Aging Research is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term. For more than 30 years, the Alliance has guided efforts to substantially increase funding and focus for aging at the National Institutes of Health and Food and Drug Administration; built influential coalitions to guide groundbreaking regulatory improvements for age-related diseases; and created award-winning, high-impact educational materials to improve the health and well-being of older adults and their family caregivers. For more information, visit www.agingresearch.org (https://www.agingresearch.org).

**About Vital Transformation**

Vital Transformation is a boutique consultancy firm focused on addressing the dynamic challenges of today's healthcare system. It specializes in conducting real-world economic analysis, market access research, horizon-scanning, and communications with an eye toward measuring the impact on current clinical practices in collaboration with healthcare professionals, researchers, and regulators. Vital Transformation-branded round tables, webinars, and conferences are regularly presented in partnership with global thought leaders and organisations.

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**File Attachments:**

**Alzheimers H.R. 3 Impact_FINAL (https://www.agingresearch.org/app/uploads/2021/04/Alzheimers-H.R.-3-Impact_FINAL.pdf)** (596K PDF)

**AD International Reference Pricing Letter Sign On 4.22.21 (https://www.agingresearch.org/app/uploads/2021/04/AD-International-Reference-Pricing-Letter-Sign-On-4.22.21.pdf)** (159K PDF)