

VoA Oral Comments – FDA Open Public Hearing on Rexulti for the treatment of agitation associated with Alzheimer's dementia

Speaker: Jim Taylor

My name is Jim Taylor, and I am the President and CEO of Voices of Alzheimer's. The mission of VoA is to empower people living with or at risk of Alzheimer's and other cognitive illnesses to drive equitable access to innovative care and treatment.

This is my wife Geri who was diagnosed with Alzheimer's over 10 years ago. She participated in the **aducanumab** clinical trial for seven years; I have been an FDA appointed patient advocate and have served on previous Alzheimer's adcoms.

I'm not here to speak about research, as there are others far more qualified in this forum to do so, but I know there have been considerable advances in the last decade in atypical anti-psychotic medicines. I'm here to speak on behalf of the people living with Alzheimer's and their care partners, especially those patients in the moderate or severe stages of the disease who have the greatest degree of unmet needs.

These treatments help control symptoms, like agitation and aggressive behavior, that can be distressing or even lead to injury to patients or care providers. For those who need treatments of this kind, they are invaluable. This new indication is particularly promising for people with Alzheimer's because it has been studied for them, and with your approval will be the first treatment with a label to reflect how it can be part of a care and treatment plan.

The use of anti-psychotic treatments in Alzheimer's has been extensively debated, but new research specifically on the benefits for Alzheimer's patients has led to changes in how these medicines can be used effectively and with fewer side effects.

It's important that the FDA continue to embrace innovation for the care of people with Alzheimer's since in the current environment some payer bodies are using any manufactured controversy as a pretense to block patient access. It's critical that the FDA give full and unqualified support to drugs that have been developed to make the lives of people with Alzheimer's better; that is the only way that they will have access and continue to see progress in managing this devastating disease.