Meryl Comer FDA Advisory Committee Meeting November 6, 2020 Remarks as Prepared for Delivery

My name is Meryl Comer... I am a long-time caregiver and founding board member of the non-profit organization, UsAgainstAlzheimer's. I come before you today to ask you to support the approval of Aducanamab.

This distinguished panel understands the mechanisms of Alzheimer's disease and I know your responsibility is to weigh carefully the "clinical benefit" of a new therapy.

But I have lived deep inside the cruel labyrinth of this disease 24/7 for more than two decades caring for my husband **AND** my 85 year old mother in our home.

The diagnosis of Alzheimer's is often late. Smart people hide out and predictions about disease longevity are often inaccurate.

My husband... a physician and former chief of hematology/oncology at NIH... was misdiagnosed for four years while we were held hostage by bouts of paranoia, hallucinations, delusions...and aggressive behaviors uncharacteristic of his personality.

He had maintained his brain ... and it just didn't matter.

When he **was** finally diagnosed, we were told he wouldn't last 5 years. His disease was early onset. By then, he had already forgotten who I was... other than a safe face... and had no insight about his prognosis.

Traumatic episodes were followed by long plateaus as he sunk deeper into the disease. I buried him this February... 24 years later.

Like so many others, he and my mother, who passed last year just 8 weeks shy of her 99thbirthday, defined themselves through their intellect and independence. Losing it to Alzheimer's and being a burden to the family was their greatest fear.

Now Alzheimer's is coming for me and the generation of 56 million baby boomers, the oldest of whom will start turning 75 at the rate of 10,000 a day in 2021.

It should also not be lost on this panel that two-thirds of Alzheimer's victims are women.

Now on the horizon... are blood tests and predictive artificial intelligence that could identify Alzheimer's disease 10-20 years before first symptoms. These advances support the importance of early therapeutic interventions... another reason... Aducanamab is a treatment worth putting on the market.

Today, the diagnosis of Mild Cognitive Impairment is still an uncertain and treacherous journey. The prognosis is numbing. You scramble to adapt to the new normal; you fight depression. You brace yourself for what's next.

So, I ask the committee to think about...what is time worth when you are tethered to a diagnosis where you slowly lose your intellect, independence, and the very essence of who you are as an individual?

Those who are eligible must be given the chance to "buy time". Let them work with their physician to decide if the risk is worth its potential benefit. Don't deprive them of the chance...to maintain cognition...and not deteriorate further... until the next wave of scientific discovery offers new options... new hope.

The unmet need is obvious. Please take every measure to bring this therapy forward. We don't expect guarantees. All we ask is the chance for more time... up front and ahead of our fate.

That...for millions of patients and their families... is clinically meaningful.

Thank you.