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Written Testimony

**United States House Committee on Ways and Means, Health Subcommittee Hearing on
"Examining Policies that Inhibit Innovation and Patient Access"**

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Chairman Buchanan, Ranking Member Doggett and members of the Subcommittee, thank you for the opportunity to testify before you today to share my story about what access to innovative breakthroughs means to me: more time with my wife, kids and grandkids. My name is Tony Gonzales. I am from Santa Maria, California, I am 48 years old, and last year I was diagnosed with mild cognitive impairment. I know this disease can destroy careers, relationships, and every day it robs me of more and more of my memories. But I stand here today to tell you, this disease does not define who I am. I am living my best life with MCI, and using every opportunity to share my story as my way of fighting back.

A few years ago, my family and I noticed the first few signs that something was wrong. I found myself having difficulty with my work as a development manager for the American Cancer Society. Others were noticing too. My family, friends, coworkers, clients, all were making excuses for my actions. Then one day I got lost coming home from work. I was in my hometown, I was in my car, on a road I had driven thousands of times - and I had no idea where I was, where I had been or where I was going. All I knew was that I needed to call my wife for help.

Another turning point was when I was at home with my family. I came in from outside and saw an open package on the kitchen table addressed to me. I was excited, because I had been waiting for some special American Flag socks that I was going to wear for my son's wedding. I reached in and pulled out my new pair of fun socks, then I excitedly showed them to my family. They looked at me like my head had just blown off – apparently just five minutes before, I had done the same exact thing. At the time, we thought my forgetfulness was due to being stressed and tired.

I spent the next couple of years bouncing from my general practitioner to UCLA, then finally to UCSF. I realize now that my experience was much more complicated due to my age: I was fighting a stigma that dementia only affects people over 65. Despite numerous MRIs, a spinal tap, sleep studies, two neuro psych exams, and a CT scan, I was told by medical professionals that I was too young to have dementia, and instead my symptoms were attributed to sleep apnea.

Following that incorrect diagnosis, I made an effort to get healthier and to eliminate what I had been told was the problem, I lost over 180 pounds. Unfortunately, my issues persisted after the

weight loss, and I had to go back to seeking an accurate diagnosis. Two years after my initial symptoms, I finally received one: mild cognitive impairment (MCI).

I sometimes think about how this process could have been smoother, or gotten me to the right information without losing so much time. For example, I didn't know at the time of my early symptoms that my Grandmother had passed from complications due to dementia and there were other family members who showed signs but never were addressed. The Hispanic culture I was raised in is not one that understands this disease and it was always dealt with shame and secrecy.

I live in a beautiful part of California. My hometown of Santa Maria sits in between Los Angeles and San Francisco. But in order for me to get the quality of care needed, the newest tests and be a part of the latest study we have to travel to one of these two cities. Living with this disease makes it very difficult to travel and then you throw the COVID years on top of it...I can tell you...it has been a very difficult couple of years for my wife and me.

I became a member of the Alzheimer's Association Early Stage Advisory Group to help raise awareness of this disease - especially for people who are under the age of 65 and not typically the "face" of Alzheimer's disease. When I'm in a meeting and someone tells me they've never met someone living with Alzheimer's disease, I say to them "now you have." I want people to see the impact this disease has on real people and families.

I, like many others who are diagnosed with MCI or dementia, was offered little direction about what to do, other than get our affairs in order and to pretty much go live a life of forgetting. It would give us so much hope to have the opportunity to access treatments that can give us more time - I'd like the chance to make the decision if the treatments are right for me and my family instead of the Centers for Medicare & Medicaid Services (CMS) just saying no.

Over the last few years, there has been incredible progress in the Alzheimer's research space thanks to the bipartisan support in Congress. The historic increases in funding at the NIH are starting to pay off: over the last year and a half, we've seen two treatments get approved by the Food and Drug Administration (FDA) and another one that will submit to the FDA later this year! These treatments have the ability to change the course of this disease. The fact that these treatments exist and are approved by the FDA and yet people like me cannot access them because Medicare refuses to cover them is frustrating and humiliating.

The benefits of these treatments will only be realized if patients have access. The treatments in this class give people more time at or near their full abilities to participate in daily life, remain independent and make future health care decisions. Treatments that deliver these benefits are as valuable as treatments that extend the lives of those with other terminal diseases.

As many of you know, under the national coverage determination (NCD) currently in place, CMS would only cover monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (mAbs) through Coverage with Evidence Development (CED). This means

for the accelerated approval pathway treatments individuals must be enrolled in randomized clinical trials (none of which exist because they have been completed) and for treatments approved through the traditional approval pathway treatments patients must be enrolled in prospective comparative studies. This decision creates even more of a barrier to care for Americans, especially individuals living in rural and underserved areas - just like my hometown. Restricting access as CMS is doing - makes it nearly impossible for many people to even have the opportunity to talk with their doctors about these treatment options.

Additionally, this NCD applies to drugs approved as of April 2022 AND all future drugs in this class. Medicare has never done that before - they've never pre-judged treatments by restricting access before anything is even approved by the FDA. CMS has repeatedly pledged to move quickly to modify the NCD if warranted by new evidence — which they have failed to do to date. They've been presented with a myriad of new evidence including peer reviewed journal articles discussing the treatments and a letter from over 200 clinicians and researchers about the efficacy of the treatment. Medicare refusing to cover FDA-approved Alzheimer's treatments has a ripple effect as well - private insurance follows Medicare's lead. If Medicare won't cover, chances are that other insurance won't cover either. Thus taking more time away from people including those who aren't on Medicare.

Based on projections from the Alzheimer's Association, more than 2,000 individuals aged 65 or older transition per day from mild dementia due to AD to moderate dementia due to AD, and therefore outside the anticipated indicated population of these treatments. Given the progressive nature of this terminal disease and the absence of treatment alternatives, delays would deny these Medicare beneficiaries the opportunity to benefit from this treatment. As of May 10, that number is approximately 248,000 people who have progressed past the point of eligibility for Leqembi since it was first approved on January 6. Keep in mind, this number doesn't include people like me who are under 65 and eligible for this treatment.

In March 2023, the U.S. Veterans Health Administration announced that it would cover the FDA-approved Leqembi (le-kem-bee). This decision will allow veterans living with mild cognitive impairment and early stage Alzheimer's disease to access medically necessary and beneficial treatments. Each day matters when you're living with Alzheimer's, this is a great opportunity for our veterans. The coverage decision made by the VHA is in sharp contrast to CMS which continues to block medically necessary and beneficial treatments to Medicare beneficiaries.

Earlier this year nearly 100 bipartisan members of Congress - in both the House and Senate - including many on this Committee - sent letters to CMS and HHS, raising concerns with CMS's coverage policies around these FDA-approved Alzheimer's treatments. As recently as last week, another company announced positive top line results for their anti-amyloid treatment, donanemab. Thankfully they and others are continuing to research this area even though Medicare refuses to give access to people like me.

This moment, in addition to the new data announced this month regarding donanemab, will provide CMS with a new opportunity to initiate a reconsideration. I am not asking for any

commitments to the outcome of such a reconsideration process. It is the initiation of the process itself that is crucial. Declining to reopen the NCD upon traditional approval would further escalate the stark and expanding divide between CMS on one hand and the FDA and VA on the other, as well as between CMS and the Alzheimer's community.

Americans living with Alzheimer's disease are entitled to FDA-approved therapies, just as are people with conditions like cancer, heart disease and HIV/AIDS. They deserve the opportunity to assess in partnership with their health care provider if an FDA-approved treatment is right for them. People are losing the opportunity, they're losing days, weeks, months, and memories. They're losing time. And it is unacceptable.

More time is more than just the number of months or years. I wake up every day hoping to know who I am, who my wife is, who my kids are. If I do that, it's a win. I live for today. I want more time to be with my grandson. Take him to the park - and be able to do that on my own. I can't drive anymore, but I can still hang out with him and spend time with him. When you get a death diagnosis, life really becomes clear to you. Having more time means everything to me - it would allow me to walk my daughter down the aisle, meet another grandchild, it gives me another chance at living my best every single day. Time to live again. Time to hope again.

I am honored to speak with you today and share my story. I hope it inspires you to continue your work in urging CMS to treat those with Alzheimer's fairly. And lastly, I hope you remember to live for today, love those around you, and I wish you good brain health. Thank you!