United States House Committee on Energy and Commerce, Health Subcommittee Hearing on "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology"

July 18, 2023

Chairman Guthrie, Ranking Member Eshoo and members of the Subcommittee, thank you for the opportunity to testify before you today to share my story about my experience caring for my mother who lived with Alzheimer's disease for 11 years. My name is Sue Wronsky. I am from Potomac, Maryland, although I grew up in Syracuse, New York. I am here today on behalf of my late Mother, Lynn, who died from Alzheimer's in 2002, and my late father, Marty, who cared for her from the beginning of her devastating diagnosis to the very end.

After several years of struggling with my mom's symptoms of early dementia, my parents finally received the unwelcome diagnosis of Alzheimer's in 1991 when she was 63. She had what is called early, or younger-onset, Alzheimer's. Back then, the diagnosis process was often longer than it is now, so she had been showing symptoms of the disease for a few years before she was finally diagnosed.

Once it became clear that my Mom would no longer be able to be at home on her own, Dad retired from his high school teaching job earlier than planned and became a full-time caregiver. In fact, our entire family became caregivers. Travel plans went by the wayside, long-planned projects were put on the back burner and Mom and Dad prepared as best they could for an uncertain future. She was able, thankfully, to live at home for the 11 years that she lived with the disease, with my dad as her primary caregiver.

My dad was an incredible caregiver. He was a retired Marine, and he was always the type

where, “if you are given a problem, you deal with it and you take it on,” but he was also very willing to accept help when it was offered. It was tough on him, and yet he was such an advocate for other caregivers. In addition to his full-time care of Mom, he became one of the Alzheimer’s Association Central New York Chapter’s most active advocates, writing letters to the editor, making visits to his local legislators, taking the bus to Albany — with Mom in tow — for the annual state advocacy day, and joining me in Washington one precious time for Alzheimer’s Impact Movement Advocacy Forum in 2006. Eventually, my dad was asked to join that Chapter’s board of directors, where he served for several years. He used to say “If the caregiver crashes, everything falls apart.” Believe it or not, 6 weeks after my mom passed away my father was having triple bypass surgery because he had been ignoring his own heart issues. Caregivers will often put aside their own health issues to put loved ones first.

When my mom was first diagnosed over 30 years ago, there were no options for people living with Alzheimer’s. Over the last few years, there has been incredible progress in Alzheimer’s research thanks to bipartisan support in Congress. The historic increases in funding at the NIH are starting to pay off. In the last year and a half, we’ve seen two treatments be approved by the Food and Drug Administration (FDA). Even just this month, the FDA granted traditional approval of lecanemab for the treatment of early Alzheimer’s disease. This is the first Alzheimer’s treatment granted traditional approval that changes the underlying course of the disease. This scientific progress has been momentous in the fight against Alzheimer’s.

However, we as Alzheimer’s advocates have had to raise our collective voices to ensure Medicare covers these FDA-approved treatments. As you know, CMS issued a national coverage determination (NCD) in 2022 that limited coverage of FDA-approved treatments for Alzheimer’s disease and future ones in the same class. Through the NCD, CMS has limited access to these drugs approved under the accelerated approval pathway to individuals enrolled

in randomized clinical trials. This translated into effectively no access throughout this period. Many people with Alzheimer's -- some I know very well, and so this too is personal to me -- continued to progress faster over this time than they would have because they were blocked from access by a regrettable Medicare policy.

Now that the first drug in this class has received FDA's traditional approval, access is becoming possible through a registry. I appreciate that CMS did provide a registry option that has been described as "low touch" and they seem to have worked hard to ensure this registry now poses as little of a barrier as possible. Nevertheless, no such Coverage with Evidence Development restrictions has ever been put in place for any other FDA-approved drug, and they shouldn't be applied here either. With all of the clear evidence regarding these newer treatments, it's well past time for CMS to remove this NCD policy which is clearly outdated and yet still remains in place.

The benefits of these treatments will only be realized if patients have access. And, if there had been an FDA-approved treatment back then, my Mom may have been able to spend more time with our family and remain independent. The idea that these individuals can take a medication that can possibly help slow this disease, even for just a few months, is enormous. For those individuals who receive a diagnosis early, evidence released just this week indicates the delay in the progression of this horrible disease could be one or more years.

Patients are losing precious time every day, and they absolutely deserve the right to decide with their doctor if a treatment is right for them. For individuals living with Alzheimer's, the value of "time" while still independent is much different than those living with other chronic conditions. Americans living with Alzheimer's disease deserve full access to FDA-approved therapies, just as are people with conditions like cancer, heart disease, and HIV/AIDS. With Alzheimer's, it is

all about time, and the last thing we need is more roadblocks: we need full access to these treatments.

I'm an advocate to honor both of my parents, but especially to carry the torch for my father who wanted nothing more than for a breakthrough to be found during his lifetime. This wasn't to be, as we lost him in 2013. But I've got some time left on this earth, and I'd like nothing more during my lifetime than to witness the end to this terrible disease that he longed to see. So, I will continue to use my voice to raise awareness and demand attention and funding from our government.

Thank you very much for the opportunity to testify here today and I look forward to answering any questions the Subcommittee may have.