

For Alzheimer's patients, a controversial drug brings hope

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At 53, Michele Hall was at the height of her legal career. She'd just sent her three kids to college. She had decades ahead with her husband Doug—after nearly 30 years of marriage, the couple looked forward to celebrating 30 more.

Then came the shocking diagnosis. Michele had Alzheimer's disease.

The illness forced her into early retirement. Michele went from legal powerhouse to full-time patient. She was forced to give up her driver's license. Her independence. Her supersonic reading ability. Her family's days became consumed with worry about what Alzheimer's would take

next.

Michele was diagnosed younger than most, but for the better part of two years, her family has been living out a story that's not uncommon in Florida. Roughly 580,000 Floridians have Alzheimer's, a disease that causes dementia and leads patients to lose brain function over time.

If Hall's condition came as a shock, it also came during a unique moment for Alzheimer's patients—a moment of hope, and controversy.

Last year, the U.S. Food and Drug Administration preliminarily approved a drug that might not just ease the symptoms of Alzheimer's but slow the progression of the disease.

Known as Aduhelm, or aducanumab, it was the first time the agency had greenlit an Alzheimer's medication in nearly two decades.

Some Alzheimer's experts and scientists harshly condemned Aduhelm's approval. Three members of the independent committee that advised the agency on the drug, which was manufactured by Biogen, resigned in protest, with one calling it "the worst approval decision that the (Food and Drug Administration) has made that I can remember." None of the committee's members had recommended it be approved without further study.

Other doctors and advocacy groups like the Alzheimer's Association praised the agency's action as a step forward that gave patients options while tests continued.

Caught in the middle were the very people the medication was intended to help. In the fallout, the Centers for Medicare and Medicaid Services announced in April that it would not cover the cost of Aduhelm for most patients.

Families like the Halls must now decide if they want to pay out-of-pocket—a whopping \$28,000 a year—for what may be, in the relatively hopeless field of Alzheimer's treatments, a miracle drug. A chance to slow the spread of a disease that robs people of the very code of who they are.

Or it may have no benefit at all.

Devastating diagnosis

Two years ago, Michele was like any other striving, well-to-do Manatee County professional. She had a house in Bradenton's suburbs. Three grown children. A demanding job as the general counsel for the Manatee County Sheriff's Office.

But slowly, starting around four years ago, the firm grip she had on her life began to loosen. First, it was imperceptible: she'd forget some paperwork here or there. But eventually, it got so bad that major events like court dates began slipping from her mind.

In late 2019, she went to see a doctor. She remembers trying to fill out the intake form and seeing a series of parallel lines instead of words.

In early tests, she was given more or less a clean bill of health. That's a [common experience](#) for many Alzheimer's patients: the frustrating, circuitous path to a diagnosis.

But in November 2020, Michele visited Jackson's Mayo Clinic for a spinal tap. Doctors assured the couple it was a housekeeping test—given her [family history](#) and age, it was unlikely Michele had the memory disorder.

Two days before Thanksgiving, Doug, who was handling his wife's

medical information, opened his email: Michele had Alzheimer's.

Doug spent the holiday weekend quietly relaying the news to their children. That Sunday, he and the kids gathered in their spacious living room and told Michele about her diagnosis.

"It's the hardest thing I've ever done," said her husband. "How do you tell your partner of 28 years they have a terminal disease?"

At first, Michele, whose family had no history of Alzheimer's, didn't know how to take it. Once she accepted it was true, she struggled for weeks with how to move forward.

She found a community of survivors like her and began speaking out about her diagnosis to congressmen, state legislators, anybody who would listen.

She became active with the Florida Alzheimer's Association. She and Doug became obsessive consumers of news about treatment options that could soon be available.

Then, in June 2021, the FDA made their dreams come true.

Experts divided

Many people say the cruelest part of Alzheimer's is its uncertainty.

At first, it's not knowing if an early symptom—a misplaced word or set of keys—is merely a sign of fatigue or something worse. After diagnosis, it's the precarity of how much time is left—before a person's sense of humor fades into fog, before a child's name, then their face, slips away forever.

A year after its approval, the cost and efficacy of Aduhelm is adding more uncertainty for those living with Alzheimer's.

And that's if they can get it.

Experts agree Aduhelm decreases the amount of amyloid plaque in the brain—a substance believed to be linked to the progression of the disease.

But it's unclear if Aduhelm's ability to attack amyloid plaque actually slows advancement.

Two large clinical studies of the drug produced conflicting results: One found possible evidence that patients taking Aduhelm experienced slower cognitive decline, the other found the drug had no benefit. Biogen ended both studies early.

The Food and Drug Administration granted "accelerated approval for Aduhelm—meaning there was some clinical evidence to suggest it may benefit patients. If future tests fail to prove the treatment's efficacy, the agency could pull Aduhelm from the market.

Dr. Dennis Selkoe, a professor of neurologic diseases at Harvard Medical School and Brigham and Women's Hospital, said it's reasonable to think Aduhelm will do what it intends to do.

"All evidence suggests that amyloid builds up to high levels first," said Selkoe, a leading researcher on the molecular basis of Alzheimer's. "Therefore, lowering amyloid levels, in my view ... should ultimately translate into less decline in patients."

He understands why people have issues with the data. "But I think that this is a case where perfection is the enemy of the possible—we are

trying hard to get something that helps millions of people who are losing their most human qualities," he said.

Lon Schneider, director of the Alzheimer's Disease Research Center at the University of Southern California, looks at Aduhelm's current data and reaches a different conclusion.

There's a good chance the drug has no benefit, he said. In trials, roughly 40% of patients who received high doses experienced either brain bleeding or swelling.

"If you're asking, 'Who would I prescribe (Aduhelm) for?'" Schneider said. "That would be no one."

'I might as well try'

The Halls know the science is mixed. To them, there's a shot the drug works—and if you had a chance, no matter how minuscule, wouldn't you take it?

"There's nothing else out there," said Michele, referring to the limited options for Alzheimer's medications. "So I might as well try this."

For an hour and a half each month, at a clinic nestled between an acai place and a yoga studio on 4th Street in St. Petersburg, the couple watches "Friends" reruns as an IV injects Aduhelm into Michele's arm.

For many, the treatment's price tag alone has created an insurmountable hurdle. It costs more than average year of tuition at a public university.

"Now no one, including myself, can afford it," said Barbara Charles, a 65-year-old Orlando resident who was diagnosed with Alzheimer's in her late fifties. "It's just about what I get for my Social Security each

month—so you get the medication, but you can't live."

"What was the point of spending gazillions of dollars on creating this drug if now it's just sitting on the shelves?" she added.

A Biogen spokesperson noted that while coverage is limited for many, Aduhelm is commercially available through some private insurance. Alzheimer's patients who meet eligibility requirements can also enroll in the company's upcoming trials for the drug, he added.

Participants have a 50-50 chance of receiving a placebo for the duration of the study, however, which could span years. The Halls didn't want to take the gamble on Michele's condition further deteriorating during that time.

"We feel bad, because obviously there's tons of people who can't afford that," Doug said. "But we'll do anything we can to invest in Michele's future."

Michele said she has not experienced any side effects so far.

Two treatments in, the couple received surprising news: Biogen was going to cover the rest of Michele's regimen.

That's because the company decided to provide Aduhelm for free to all patients who began treatment before April 8 of this year, according to a Biogen spokesperson.

More treatments on way

Let's say Aduhelm is not the answer Alzheimer's patients have been waiting for. Could donanemab be the next great hope? Gantenerumab?

Trial data for these, and several other upcoming treatments designed to attack amyloid plaque, are expected to come out this month.

"If one of these other drugs shows statistically significant effects, that brings new life back into this," said Schneider of the University of Southern California.

One already shows promise.

Two weeks ago, Biogen and the Tokyo-based Eisai announced that lecanamab, another Alzheimer's drug they're developing, slowed cognitive decline in patients in a large, late-stage clinical trial.

Though the drug has not yet been approved, its results provide the strongest evidence to date that removing plaque can slow the disease.

The Alzheimer's Association called the findings "the most encouraging results in clinical trials treating the underlying causes of Alzheimer's to date."

Doug believes Alzheimer's will one day be like HIV—a diagnosis that was once a death sentence, but can now be managed with a medication so effective at slowing its progression it allows people to live healthy lives, free of symptoms.

But the clock is ticking for his wife, who sometimes has a harder time feeling Doug's hope.

"He'll tell you the sun is shining when it's not," Michele said.

"No, it is shining," her husband replied with a smile. "You're just looking at it wrong."

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