

## New Alzheimer's Drug: Aduhelm

By Pamela R. Kelley

On June 6, the Food and Drug Administration granted approval for a new medication, aducanumab (marketed as Aduhelm). This is the first drug ever approved that is designed to modify the disease. Prior FDA-approved pharmacological treatments were designed to ease symptoms. This drug is designed to alter the course of the disease by slowing the deterioration that occurs in the brain.

Those living with Alzheimer's disease, their family caregivers, and the advocacy community express relief, happiness, and optimism regarding the first new drug to treat Alzheimer's disease since 2003. Harry Johns, president and chief executive of the Alzheimer's Association, described the FDA approval as "a victory for people living with Alzheimer's and their

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## Comfort Pets Help Reduce Isolation for Any Alaskan Living with Alzheimer's or Related Dementias

By: Alzheimer's Resource of Alaska

Are you worried about someone who is lonely and needs comfort? This might help.

Isolation and loneliness are just two hurdles people living with Mild Cognitive Impairment (MCI), Alzheimer's disease or related dementia (ADRD) regularly face. There are supports and

resources throughout Alaska that address these issues. One of the latest is our Comfort Pet program. Comfort Pets, designed by the company Joy for All, are robotic cats and dogs designed to bring comfort, companionship and fun to elders.

They are fantastic

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## Rebecca Ann Clement

3/31/1950 – 6/14/2021



Rebecca Ann Clement (above) founded our organization with her sister, Beverly Tallman, in 1983.

Becky passed away at 8:30am, June 14, 2021.

A Celebration of Life will be held at Arctic Valley Ski Area Lodge, Friday July 16th, 2021 at 7pm. Please RSVP [here](#).

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## New Alzheimer's Drug: Aduhelm *(Cont. from page 1)*

families.”

Jeff Borghoff, a New Jersey resident who has lived with younger-onset AD for five years and who participated in the clinical trials, told the Washington Post, “This is epic news. Now, I may have time to watch my kids get married. My wife said, ‘I have more time with you now.’”

Marc Archambault was one of the first patients to receive Aduhelm outside of the clinical trials. Just before he got his first infusion at the Butler Hospital in Providence, R.I., he told the reporter, “The thought that the last stage [of Alzheimer’s]

may now be far away for me, or even that I might stay as I am, is incredible.”

The manufacturer, Biogen, reports that they are working with four sites in Alaska to provide the treatment: Peak Neurology, Alaska Neurology Center, Denali Health Care Specialists and Corvus Neurology.

The elation among AD patients and their families hasn’t been widely matched by the scientific community, however. In the month following the FDA’s approval, most of the media coverage has centered on criticism of the FDA’s decision. Why is that? The answer rests in

part with understanding the nature of the FDA approval, and the process by which it arrived at approval.

### Accelerated Approval, not Full Approval

The FDA explicitly acknowledged uncertainty about the effectiveness of Aduhelm. For that reason, it did not grant full approval. Instead, the FDA approved the drug under the “accelerated approval” standards. Biogen was directed to conduct a post-approval study to confirm that the drug demonstrably slows cognitive deterioration.

*(Cont. on page 4)*



Dear Friends,

Everything seemed a little sunnier to me after June 1, when we returned to meeting in person with those of our clients and families who prefer to come to our offices for assistance. The chimes from the doorbell, the voices in the hallways, and increased staff presence add to an atmosphere of normalcy that all of us have sorely missed. We anticipate a return to small gatherings like Art Links, Mind Matters, and Support Groups in August. They may be slightly different, but will be familiar.



Since my last letter, the Food and Drug Administration (FDA) approved Biogen's drug, aducanumab (marketed as Aduhelm), for treatment of Alzheimer's disease (AD). The FDA decision was controversial, yet the fact remains that this drug is the first in 18 years that has been approved for the treatment of AD. It's also the first drug that targets a suspected underlying cause of the disease. It's not a cure. It doesn't stop AD in its tracks. But it offers the prospect of slowing disease progression in those with Mild Cognitive Impairment (MCI) or mild dementia. For that alone, advocacy groups, persons living with dementia and their care partners are heartened by this development. There's an [article](#) on the cover page to learn more about this new drug, and pointing to sources for detailed information.

This month also carried with it a passing of note. Becky Clement passed away on June 14. Becky was one of the incredible sisters whose determination to improve the lives of Alaskans affected by dementia led to the formation of Alzheimer's Resource of Alaska in 1984. She and her sister, Beverly Tallman, embodied that Alaskan spirit that saw a need that could be filled, rolled up their sleeves, and got about the business of filling it. Our sympathies go out to Becky's family. Information about her Celebration of Life is on the [cover page](#).

With gratitude for your continued support,

Pamela Kelley  
Executive Director

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# Comfort Pets Help Reduce Isolation for Any Alaskan Living with Alzheimer's or Related Dementias

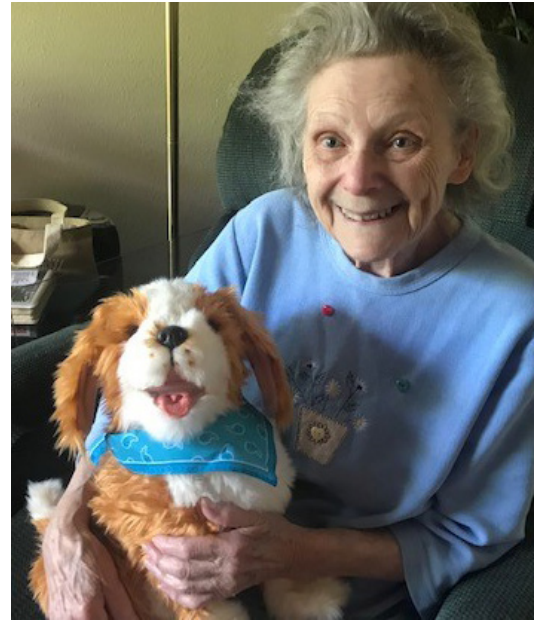
*(Cont. from page 1)*

companions that don't require the care of live pets. In fact, several ARA staff were surprised when they walked through the conference room where some comfort pets were on display and the pets moved, meowed or barked for attention! When one fell over they were surprised to see it right itself. These "pets" are truly incredible feats of technology and comfort.

Alzheimer's Resource of Alaska is now providing a limited number of comfort pets at no cost to reduce social isolation for Alaskans. Funding was provided by the CARES Act, administered by the State Department of Health and Social Services,

Division of Senior and Disability Services (DHSS/SDS).

To be considered for the Comfort Pet program applicants must have dementia or suspected dementia and live in the community, outside of residential care, at the time of application. Here is the link to apply <https://www.alzaska.org/comfort-pet-application>. Individuals living with ADRD who live in an assisted living or nursing home and would like/benefit from a Comfort Pet are encouraged to apply for a Mini-grant to get one: <https://www.alzaska.org/resources/mini-grants>.



*Comfort Pet recipient who just received her new dog. "She loved it!" according to her family.*

If you have questions about this program, please contact Kevin Silver at [ksilver@alzaska.org](mailto:ksilver@alzaska.org) or 907-561-3313. ★

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## New Alzheimer's Drug: Aduhelm *(Cont. from page 2)*

This post-approval study will last nine years, and if it doesn't prove clinical benefit, the FDA's accelerated approval could be withdrawn.

Dr. Patrizia Cavazzoni, Director of the FDA Center for Drug Evaluation and Research, provided a post on the FDA website explaining the agency's decision. She

explained that in the two Phase 3 trials conducted with Aduhelm, the medication consistently reduced the level of amyloid plaques in the brain. FDA is persuaded that it is reasonably likely that this reduction will result in clinical benefit.

She also explained that the FDA's Accelerated Approval

Program was established to allow for earlier approval of drugs that treat serious conditions and that fill an unmet medical need. Approval is based on an intermediate measure – here a biomarker that is thought to predict clinical benefit but is not itself a measure of clinical

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## New Alzheimer's Drug: Aduhelm *(Cont. from p4)*

benefit. In this instance, it is the declining presence of amyloid-beta in PET scans and cerebrospinal fluids in the Phase 3 trial participants. It's not a measure of clinical benefit by itself, but rather a predictor.

That uncertainty of demonstrated clinical benefit is the reason why this drug, approved under the Accelerated Approval Program, will be subjected to a Phase 4 confirmatory trial. If that 9-year study doesn't verify the predicted benefit, the FDA could remove the

drug from the market.

Dr. Cavazzoni noted the urgent need for Alzheimer's treatment for the more than 6 million Americans living with the disease today as an important factor in the FDA decision.

### Criticism from the FDA's Advisory Committee.

Aduhelm was approved even though no members of the FDA's 11-person advisory panel, the Peripheral and Central Nervous System Drugs Advisory Committee, considered the drug ready for formal approval. They

found that the evidence did not convincingly show that Aduhelm could slow cognitive decline in people in the early stages of the disease (the trial population) and that the drug could cause potentially serious side effects of brain swelling and brain bleeding.

The advisory panel was not consulted about the accelerated approval. In its aftermath, Dr. Aaron Kesselheim (professor of medicine at Harvard Medical School and Brigham and

*(Cont. page 6)*

## RICE University Requests Family Caregiver Volunteers for Study of Dementia Caregiver's Health during COVID-19

[Project Care](#), from Rice University, is looking for volunteers who are currently dementia family caregivers for an important research study on examining the impact of emotions on caregivers' health.

The goal of this remote research study is to find out more about dementia caregivers' mental and physical health during COVID-19.

To be eligible you must

care for a relative at least 4 hours daily for the last 3 months, own a cell phone with a data plan, and have access to a computer with internet.

Participants will take online screening surveys, complete daily cell phone surveys over 3-weeks and wear a provided smartwatch.

The study is offering up to \$255 compensation for your time.

Details can be found

here: <https://bmed.rice.edu/current-projects/project-care/>

Additional eligibility criteria applies. To determine study eligibility: <https://tinyurl.com/ProjectCARE-screener>

If you are interested or would like more information please contact BMED Lab at 832-819-4297 or email [careduringCOVID@rice.edu](mailto:careduringCOVID@rice.edu).

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# New Alzheimer's Drug: Aduhelm *(Cont. from page 5)*

Women's Hospital), Dr. Joel Perlmutter (a neurologist at Washington) University School of Medicine in St. Louis), and Dr. David Knopman (clinical neurologist at the Mayor Clinic) – all members of the advisory committee, resigned their positions on the committee.

These experts stated that they believed the evidence for Aduhelm's benefit was weak, that the FDA erred in approving the drug for anyone with Alzheimer's at

any stage rather than individuals at early-stage Alzheimer's or mid-cognitive impairment, as were included in the clinical trials. They also noted there was insufficient evidence that reducing amyloid can help patients by easing their memory and thinking problems.

## Cautious Clinicians

The Alzheimer's Association convened a forum on June 14 to answer questions about the use of Aduhelm. Dr. Stephen Salloway, director of neurology and the memory and



*Microbiology Researcher studying organisms under microscope – Stock photo*

*(Cont. [page 8](#))*

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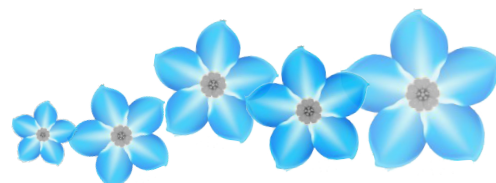
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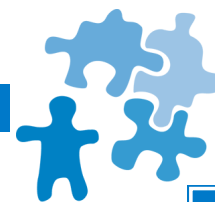
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## New Alzheimer's Drug: Aduhelm *(Cont. from page 6)*

Aging Program and Butler Hospital in Providence, R.I. emphasized that the use of Aduhelm should be limited to certain patients: those in early stages whose brains contain high levels of amyloid. He said doctors should use the drug only for patients whose statuses match those in the

clinical trials. "There's no evidence that it could be beneficial for any other stage of Alzheimer's," he said.

The panelists suggested that, at least at the outset, relatively few doctors and clinics would have the ability to adequately diagnose, screen, and treat patients.

"This is not a simple medication to use," said Dr. Paul Aisen, director of the Alzheimer's Therapeutic Research Institute at the University of Southern California who advocated for the drug's approval. "I think that establishing the

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# New Alzheimer's Drug: Aduhelm

(Cont. from page 8)

appropriate individuals for treatment, and monitoring treatment, requires knowledge and benefits from experience, and there are very few clinicians who have this experience.”

The panelists reportedly devoted considerable discussion to the risks associated with Aduhelm: brain swelling and hemorrhages. These occurred in about 40% of those who received the high dose in the two large clinical trials.

It will be important to have comprehensive discussions with patients and families about “how to weigh the inconvenience and cost and risk against the possible benefit, according to Dr. Aisen. “Managing expectations is a huge challenge here. Our expectation is a modest slowing of the rate of decline. It’s impossible to determine on an individual patient level whether someone is benefiting or not.”

There are, right now, 94 separate clinical trials in the process of working

on disease-modifying treatments for Alzheimer’s disease. Some are focused on the amyloid theory underpinning Aduhelm. Others are focused on tau; still others on inflammation.

The cause of Alzheimer’s remains an elusive scientific fact, and the research continues.

For now, there is the promise of Aduhelm for those with access. More on that in another article, as the payer picture clarifies. ★

## Sources:

[FDA’s Decision to Approve New Treatment for Alzheimer’s Disease – FDA.gov](#)

[FDA approves first drug intended to slow cognitive decline caused by Alzheimer’s disease – washingtonpost.com](#)

[The controversial approval of an Alzheimer’s drug reignites the battle over the underlying cause of the disease – washingtonpost.com](#)

[Three F.D.A. Advisers Resign Over Agency’s Approval of Alzheimer’s Drug – nytimes.com](#)

[Many Alzheimer’s Experts Say Use of Aduhelm Should Be Sharply Limited – nytimes.com](#)

## Alaska Caregiver Support Groups

### Statewide

Every 1st Sat, 1-2 pm - Every 3rd Wed, 1-2 pm  
Dial in using [1-877-216-1555](tel:1-877-216-1555), Code 927989#.  
For additional information, contact Gay Wellman, [907-822-5620](tel:907-822-5620) or [800-478-1080](tel:800-478-1080)

### Anchorage

Every 4th Thursday, 5:30-7 pm  
CONTACT: Debbie Chulick, [907-561-3313](tel:907-561-3313)

### Eagle River

Every 2nd Thursday, 5-6:30 pm  
CONTACT: Debbie Chulick, [907-561-3313](tel:907-561-3313)

### Fairbanks

Every 2nd Tuesday, 4:30-6 pm  
Every 3rd Tuesday, 1:00-2:30 pm  
CONTACT: Joan Adams, [907-452-2277](tel:907-452-2277)

### Homer

Every 2nd & 4th Thurs, 2:30-3:30pm  
CONTACT: Pam Hooker, [907-235-7655](tel:907-235-7655)

### Juneau / Southeast

Every 1st & 3rd Thursday 12 -1 pm  
CONTACT: Aimee [907-463-6177](tel:907-463-6177)

### Ketchikan

Call for current schedule.  
CONTACT: Bernice, [907-255-8080](tel:907-255-8080)

### Kodiak

Every 4th Thursday, 12:30-1:30 pm  
CONTACT: [907-486-6181](tel:907-486-6181)

### Mat-Su Valley

Every 2nd Tuesday, 1:30-3 pm  
CONTACT: Janice Downing [907-746-3413](tel:907-746-3413)

Every 1st Friday, 10-11:30 am  
CONTACT: Kim Jung, [907-746-3413](tel:907-746-3413)

### Seward

Every 4th Thursday, 1-2 pm  
CONTACT: [907-244-5604](tel:907-244-5604)

### Sitka

Call for current schedule  
CONTACT: [907-747-4600](tel:907-747-4600)

### Soldotna

Every 2nd and Last Tuesday, 1-3 pm  
Every 1st Tuesday, 1-2 pm  
CONTACT: Dani Kebschull, [907-262-1280](tel:907-262-1280)

### Talkeetna

Every 1st Monday, 10-11:30 am  
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### Willow

Every 1st Monday, 1:30-3 pm  
CONTACT: Kim Jung, [907-746-3413](tel:907-746-3413)

# Classes & Events around the State

Classes and events are being offered via Zoom statewide. All classes require registration.

## "Normal" Aging vs "Not-Normal" Aging

Mon, 7/12, 1p-2:30pm

**REGISTER HERE**

## Downsizing & Decluttering

Tues, 7/20, 5:30pm-7p

**REGISTER HERE**

## Honoring Connection: How to Improve Communication

Fri, 7/23, 1pm-2:30pm

**REGISTER HERE**

## Helpful Tips & Strategies for Managing Memory Loss

Tues, 8/10, 1-2:30p

**REGISTER HERE**

## Communication Tips: Beyond the Basics

Sat, 8/14, 1-2:30p

**REGISTER HERE**

## End of Life Decisions

Fri, 8/20, 1-2:30pm

**REGISTER HERE**

## Intimacy, Sexuality, & Dementia

Sat, 9/11, 1-2:30p

**REGISTER HERE**

## Frontotemporal Disorders

Tues, 9/14, 1-2:30pm

**REGISTER HERE**

## Making Visits Positive

Fri, 9/17, 1-2:30pm

**REGISTER HERE**

## What About The Kids? Dementia Through the Eyes of a Child

Tues, 9/21, 5:30-7pm

**REGISTER HERE**

## Memory Café

Thursdays 1-2 pm

7/8, 8/12, 9/9



Register with:

Ann Farris at

[907-561-3313](tel:907-561-3313) or  
[afarris@alzalaska.org](mailto:afarris@alzalaska.org)

## Art Links

Thursdays 1-1:45pm

7/1, 7/15, 8/5,

8/19, 9/2, 9/16



Register with:

Janice Downing at

[907-746-3413](tel:907-746-3413) or  
[jdowning@alzalaska.org](mailto:jdowning@alzalaska.org)

## Savvy Caregiver

Tuesdays 1-3 pm

6/22-7/27

**Screening &  
Pre-registration  
required**

Register with:

Janice Downing at

[907-864-3408](tel:907-864-3408) or  
[jdowning@alzalaska.org](mailto:jdowning@alzalaska.org)

## **Voices** of the **Last Frontier**

Chorus for Alaskans living with dementia and their care-partners.

Register with:

Ann Farris:

[907-561-3313](tel:907-561-3313) or  
[afarris@alzalaska.org](mailto:afarris@alzalaska.org)

## Mind Matters | Brain Works

Support for people recently diagnosed with Alzheimer's or related dementias, people living with moderate memory loss, and their care partners.

**Screening &  
Pre-registration required**

Register with:

Amy Becia

[907-561-3313](tel:907-561-3313) or  
[abecia@alzalaska.org](mailto:abecia@alzalaska.org)

## Mind Aerobics

For Alaskans worried about memory loss.

12-week session, meeting twice a week for 1 hour.

Full-brain workout designed to help people who have concerns about their memory and want to keep their mind sharp.

**Screening,  
Pre-registration &  
FEE required  
(Scholarships available)**

Register with:

Ken Helander

[907-561-3313](tel:907-561-3313) or  
[khelander@alzalaska.org](mailto:khelander@alzalaska.org)

For more information or registration assistance call: [907-561-3313](tel:907-561-3313)

## Professional Caregiver Webinars

### The Power of Music

Tuesday, 7/20, 12 pm - 1:00pm

**REGISTER HERE**

### Engaging People Living with Dementia

Tuesday, 8/24, 12 pm - 1:00pm

**REGISTER HERE**

### Engaging People Living with Dementia: The Environment

Tuesday, 9/21, 12 pm - 1:00pm

**REGISTER HERE**

Contact: Amber Smith: [907-586-6044](tel:907-586-6044) or [asmith@alzalaska.org](mailto:asmith@alzalaska.org)



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