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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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
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.alzalaska.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.alzalaska.org/resources/mini-grants.

If you have questions about this program, please contact Kevin Silver at ksilver@alzalaska.org or 907-561-3313.

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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
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

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.
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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...

In Honor & Memory of

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The family of Donald Barnhart
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### Volunteer & In-Kind Supporters

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- Anne & Tom Farris
- Gayla Designs
- Kristin George*
- Rene Goentzel
- Kevin R. Hagensieker
- Rebecca Hansen*
- Harbor 360
- Lynda Hutchins*
- Iditarod Trail Committee
- Indigo Tea
- J-Rod’s Guide Service
- Melissa Johnson*
- Kayaking Kodiak
- Kineaid Grill
- Krav Maga
- Martial Arts Training
- Mike Lajoie*
- Melissa Liebner*
- Sabrina Peterson*
- Premier Alaska Tours
- Reindeer Farm
- Karen Scholz*
- Jill Simek*
- Mark & Mae Ann Smith
- Luann Strickland*
- The Alaska Club
- The Salt Cave
- Fred Traber*
- Rori Van Nortwick*
- University of Alaska Museum of the North
- Vent Doctors of Alaska
- Charlene Walker*

* denotes current or former ARA board member
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
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
decay 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, Code 927989#.
For additional information, contact Gay Wellman, 907-822-5620 or 800-478-1080

Anchorage
Every 4th Thursday, 5:30-7 pm
CONTACT: Debbie Chulick, 907-561-3313

Eagle River
Every 2nd Thursday, 5-6:30 pm
CONTACT: Debbie Chulick, 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

Homer
Every 2nd & 4th Thurs, 2:30-3:30pm
CONTACT: Pam Hooker, 907-235-7655

Juneau / Southeast
Every 1st & 3rd Thursday 12 -1 pm
CONTACT: Aimee 907-463-6177

Ketchikan
Call for current schedule.
CONTACT: Bernice, 907-255-8080

Kodiak
Every 4th Thursday, 12:30-1:30 pm
CONTACT: 907-486-6181

Mat-Su Valley
Every 2nd Tuesday, 1:30-3 pm
CONTACT: Janice Downing 907-746-3413

Every 1st Friday, 10-11:30 am
CONTACT: Kim Jung, 907-746-3413

Seward
Every 4th Thursday, 1-2 pm
CONTACT: 907-244-5604

Sitka
Call for current schedule
CONTACT: 907-747-4600

Soldotna
Every 2nd and Last Tuesday, 1-3 pm
Every 1st Tuesday, 1-2 pm
CONTACT: Dani Kebschull, 907-262-1280

Talkeetna
Every 1st Monday, 10-11:30 am
CONTACT: Kim Jung, 907-746-3413

Willow
Every 1st Monday, 1:30-3 pm
CONTACT: Kim Jung, 907-746-3413
## Classes & Events around the State

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

<table>
<thead>
<tr>
<th>Class/Event</th>
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<tr>
<td>Professional Caregiver Webinars</td>
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<tr>
<td><strong>The Power of Music</strong></td>
<td>Tuesday, 7/20, 12 pm - 1:00pm</td>
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<tr>
<td><strong>Engaging People Living with Dementia</strong></td>
<td>Tuesday, 8/24, 12 pm - 1:00pm</td>
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<tr>
<td><strong>Engaging People Living with Dementia: The Environment</strong></td>
<td>Tuesday, 9/21, 12 pm - 1:00pm</td>
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**Contact:** Amber Smith: 907-586-6044 or asmith@alzalaska.org

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<tr>
<td><strong>Memory Café</strong></td>
<td>Thursdays 1-2 pm, 7/8, 8/12, 9/9</td>
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<td>Ann Farris at 907-561-3313 or <a href="mailto:afarris@alzalaska.org">afarris@alzalaska.org</a></td>
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<tr>
<td><strong>Art Links</strong></td>
<td>Thursdays 1-1:45pm, 7/1, 7/15, 8/5, 8/19, 9/2, 9/16</td>
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<td>Janice Downing at 907-746-3413 or <a href="mailto:jdowning@alzalaska.org">jdowning@alzalaska.org</a></td>
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<td><strong>End of Life Decisions</strong></td>
<td>Fri, 8/20, 1-2:30pm</td>
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<td><strong>Intimacy, Sexuality, &amp; Dementia</strong></td>
<td>Sat, 9/11, 1-2:30p</td>
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<td><strong>Frontotemporal Disorders</strong></td>
<td>Tues, 9/14, 1-2:30pm</td>
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<td><strong>Making Visits Positive</strong></td>
<td>Fri, 9/17, 1-2:30pm</td>
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<td><strong>What About The Kids? Dementia Through the Eyes of a Child</strong></td>
<td>Tues, 9/21, 5:30-7pm</td>
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<tr>
<td><strong>Savvy Caregiver</strong></td>
<td>Tuesdays 1-3 pm, 6/22-7/27</td>
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<td>Janice Downing at 907-864-3408 or <a href="mailto:jdowning@alzalaska.org">jdowning@alzalaska.org</a></td>
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<td><strong>Communication Tips: Beyond the Basics</strong></td>
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<td><strong>Downsizing &amp; Decluttering</strong></td>
<td>Tues, 7/20, 5:30pm-7p</td>
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<td><strong>Honoring Connection: How to Improve Communication</strong></td>
<td>Fri, 7/23, 1pm-2:30pm</td>
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<tr>
<td><strong>Helpful Tips &amp; Strategies for Managing Memory Loss</strong></td>
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For more information or registration assistance call: 907-561-3313

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**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: Janice Downing at 907-746-3413 or jdowning@alzalaska.org

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**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 or khelander@alzalaska.org

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**Notes**

- For more information or registration assistance call: 907-561-3313

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Follow us on Social Media for the latest information.

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[Social Media Links]