

advANCES

PROGRESS IN ALZHEIMER RESEARCH AND CARE

A Vaccine for Alzheimer's?

Scientists Hope to Replicate Mouse Findings in Humans

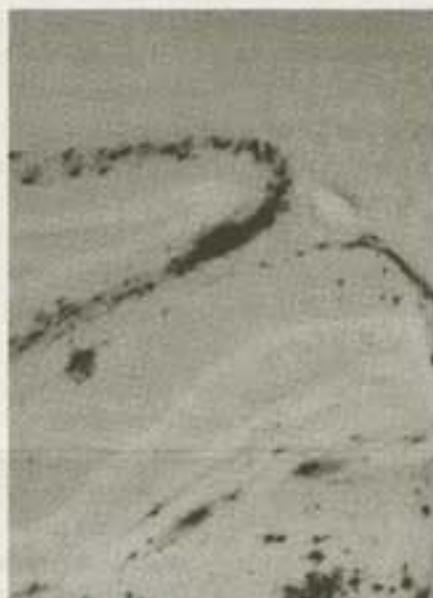
An Alzheimer vaccine tested in mice could lead ultimately to the prevention of Alzheimer's disease in humans.

"Even if the vaccine is not effective in humans, it still opens up a new area of research that will tell us more about Alzheimer's disease," says Bill Thies, PhD, vice president of medical and scientific affairs for the Alzheimer's Association.

In a groundbreaking study published in the July 8, 1999, issue of *Nature* a new compound, called AN-1792, prevented the formation of amyloid plaques in young mice and significantly reduced further plaque formation in older mice.

AN-1792 is a synthetic form of naturally occurring beta amyloid protein, which has long been identified as the primary component of amyloid plaques—one of the pathological characteristics of Alzheimer's disease.

Although amyloid plaques are found in the brains of most individuals with Alzheimer's disease, scientists



The left magnified image shows the brain of a mouse genetically engineered to produce amyloid plaques, the protein deposits characteristic of Alzheimer's disease. The image on the right shows the brain of a second mouse containing no plaques after being treated with the vaccine AN-1792.

do not yet know whether plaques are a cause or a direct result of the disease process.

"For many years scientists have hypothesized that the presence of amyloid plaques causes cell death and leads to a decline in a person's cognitive functions," explains Thies. "Now they have an opportunity to test this theory."

The current study included two separate experiments, both involving mice genetically altered to develop amyloid plaques characteristic of Alzheimer's disease (PDAPP mice).

In the first experiment, young PDAPP mice were immunized with AN-1792, while two separate control groups were given injections of either saline or another protein called serum amyloid P component, or SAP. After 13 months the three groups of mice were evaluated. The group that received the AN-1792 vaccine developed no amyloid plaques in their brains,

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Great Respect for Restraint-Free, Long-Term Care Settings

In the article on late-stage care (vol. 19, no. 2, summer 1999), the wording says, "restraints are often used in long-term care settings and hospitals as a means to control Alzheimer-related behavior problems." I am very concerned that statements like this cause greater fear and lead caregivers to delay placement of a loved one in a long-term care facility, to the point of endangering the health and well-being of the person with Alzheimer's.

As a family member of a father-in-law who died from Alzheimer's in a long-term care setting, I have great respect for the compassionate, restraint-free caregiving in long-term care settings.

*Linda Mansfield, M.S.W.
East Jordan, Michigan*

Telling Diagnosis Would Be Devastating to Wife

I'm writing in response to the letter "Much To Gain by Telling Diagnosis" that appeared in vol. 19, no. 2, summer issue of *Advances*. In my case I believe it was best not to tell my wife of her diagnosis of Alzheimer's. Her brother has Alzheimer's, and I felt it would be better for her if she did not know. It would devastate her, and I could not see any advantage of telling her. Her doctor did tell her she had memory problems and put her on donepezil.

Now my wife of 53 years lives in a health care facility that she accepts as her home and is doing as well as expected. She still doesn't know she has Alzheimer's, but I feel that I made the right decision.

*John Vogt
Webster, New York*

Correction:

On page 9 of the summer issue of Advances, vol. 19, no. 2, the second-to-last paragraph should have read, "To qualify for hospice under Medicare, a person with Alzheimer's must be diagnosed as having less than six months to live." The words for hospice were omitted. Advances regrets the error.

WE WANT TO HEAR FROM YOU!

Please share with us your experiences related to issues covered in *Advances*, or suggest topics you'd like to read more about.

November is...

National Alzheimer's Disease Month Sponsored by the Alzheimer's Association
(800) 272-3900 www.alz.org

National Family Caregivers Month Sponsored by the National Family Caregivers Association
(800) 896-3650 www.nfcares.org

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For more information on Alzheimer's disease and the Association or to be placed on the *Advances* mailing list, call (800) 272-3900. Information is also available via the Internet at <http://www.alz.org>.

Letters should be addressed to Michele Pellissier, Editor. Faxes can be sent to (312) 335-1110 and e-mail to michele.pellissier@alz.org. *Advances* does not publish unsolicited poems or short stories or accept advertisements.

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The Diagnosis: Getting the Answers You Need

At the age of 58, Matthew Blair began to have difficulty reading, speaking, and performing daily tasks at work. His wife, Isabel, was convinced that he had Alzheimer's. Believing Matthew was "too young to have Alzheimer's" their primary care physician did not screen for the disease.

After seeking help from a specialist, Matthew was eventually diagnosed as having "probable Alzheimer's disease."

The Blairs' situation is certainly not unique. Families usually turn to their primary care physicians first to diagnose Alzheimer's. Unfortunately, many physicians have not had the proper training to manage the multiple health care problems of older adults or to recognize possible signs of dementia in younger individuals.

"There is a gap in education for primary care physicians about Alzheimer's disease, especially in the early stages," says Sandra Weintraub, PhD, head of neuropsychology and director of the clinical core at the Northwestern University Alzheimer's Disease Center in Chicago.

If you are not getting the answers you need from your physician, you may need to request a referral to a specialist in Alzheimer diagnostics.

"Let your primary care physician know that you are aware that there

are resources in the community that evaluate memory loss and that memory loss can be a precursor for subsequent dementia," says Weintraub.

Keep a journal

Note the changes that have occurred in your loved one's behavior and memory and the time span during which they occurred. Also provide a list of all the medications and herbal remedies the person is taking.

"Look beyond memory loss for signs of the disease," says Weintraub.

"Consider personality and mood changes as possible symptoms."

Learn about how Alzheimer's is diagnosed

There is no one diagnostic test that can detect if a person has Alzheimer's disease. However, new diagnostic tools and criteria make it possible to make a positive clinical diagnosis of Alzheimer's with an accuracy of 85–90 percent. A complete diagnosis is based on a number of factors.

- A medical history provides information about current mental or physical conditions, prescription drug intake, and family health history.
- A mental status evaluation assesses a person's sense of time and place

SEE THE DIAGNOSIS, PAGE 11



The National Institute on Aging funds more than 29 Alzheimer's Disease Centers (ADCs) at major medical institutions nationwide. The ADCs offer you access to practitioners who specialize in diagnosing Alzheimer's disease.

R_x CORNER



New Drug Approved by the FDA

The Food and Drug Administration (FDA) recently approved rivastigmine (Exelon®) for the treatment of Alzheimer's, offering another option for affected individuals. Rivastigmine, like donepezil and tacrine, is an acetylcholinesterase inhibitor designed to slow the progression of the disease in individuals with mild to moderate Alzheimer's.

Novartis Pharmaceuticals Corporation expects this drug to be available for prescription by the end of this year, after the company receives final clearance from the FDA.

Metrifonate Back on Track with FDA

After several months of data reanalysis, Bayer Corporation has decided to resubmit its drug metrifonate (ProMem™) to the FDA for review. Metrifonate is an acetylcholinesterase inhibitor that was originally submitted to the FDA for review in late 1997. However, due to complications with their experimental data, Bayer was asked to reevaluate the results of their clinical studies and resubmit their application at a later date.

Although no estimates have been given as to when metrifonate might be approved, the FDA has promised a speedy review of the new data.

Ongoing Clinical Drug Studies

Clinical drug studies currently recruiting patients with Alzheimer's disease include:

- Donepezil (Aricept) and Estrogen
- Estrogen
- Galantamine
- Lazabemide
- Melatonin
- Propentofylline (HWA 285)
- Women's Health Initiative Memory Study of Estrogen

Studies recruiting individuals with mild cognitive impairment include:

- InDDEx Study
- Memory Impairment Study

To obtain information about these studies, contact your local chapter or call (800) 272-3900 and ask for the drug fact sheets.

who will develop Alzheimer's disease later in life so that they are sure to get the vaccine. As yet, there is no way to detect the disease in people who do not yet exhibit symptoms.

Until now, AN-1792 has been studied only in mice. Elan Corporation is planning to submit data from these experiments to the Food and Drug Administration (FDA) later this year to request permission to begin testing in human subjects. Pending FDA approval for testing, AN-1792 first

will be evaluated for safety in a small group of individuals (usually 50 or fewer). If AN-1792 is proven safe for use in humans, larger clinical studies could begin as early as the end of next year.

As with any other experimental treatment, AN-1792 will undergo several phases of clinical study. Providing all phases run smoothly and produce favorable results, AN-1792 might become available for general use within the next four to seven years.

There is currently no waiting list for individuals interested in participating in future studies of AN-1792.

However, we will make an announcement in Advances and have a drug fact sheet available as soon as clinical studies are launched. In the meantime, if you would like more information about this study or other clinical drug trials, contact your local chapter of the Alzheimer's Association or call (800)272-3900. 

Association Adopts Position on Stem Cell Research

In keeping with its mission to eliminate Alzheimer's disease, the Alzheimer's Association opposes any ban on federal funding for human stem cell research, provided that appropriate ethical and oversight guidelines are in place.

For the last four years Congress has banned the use of federal funding for any research involving the use of human embryos. More recently the U.S. Department of Health and Human Services issued a legal opinion that federal funds could be used for research involving human stem cells derived from embryos. The department took the position that because stem cells could not themselves develop into a human being, they cannot be considered embryos and do not fall under the federal ban against funding research using human embryos.

The National Institute on Aging strongly supports human stem cell research as a promising new avenue for understanding and potentially treating Alzheimer's disease. Stem cells could eventually be used to replace dying nerve cells in regions of the brain affected by Alzheimer's.

Privately owned companies are already conducting stem cell research; federal funding would provide the governmental oversight and direction that is currently lacking.

The National Institutes of Health has convened a working group that will issue draft guidelines and an oversight process for human stem cell research. Until the guidelines and oversight process are finalized, researchers will not be allowed to use federal funds to conduct stem cell research. 

VACCINE...
CONTINUED FROM PAGE 1

while the other two control groups did develop plaques.

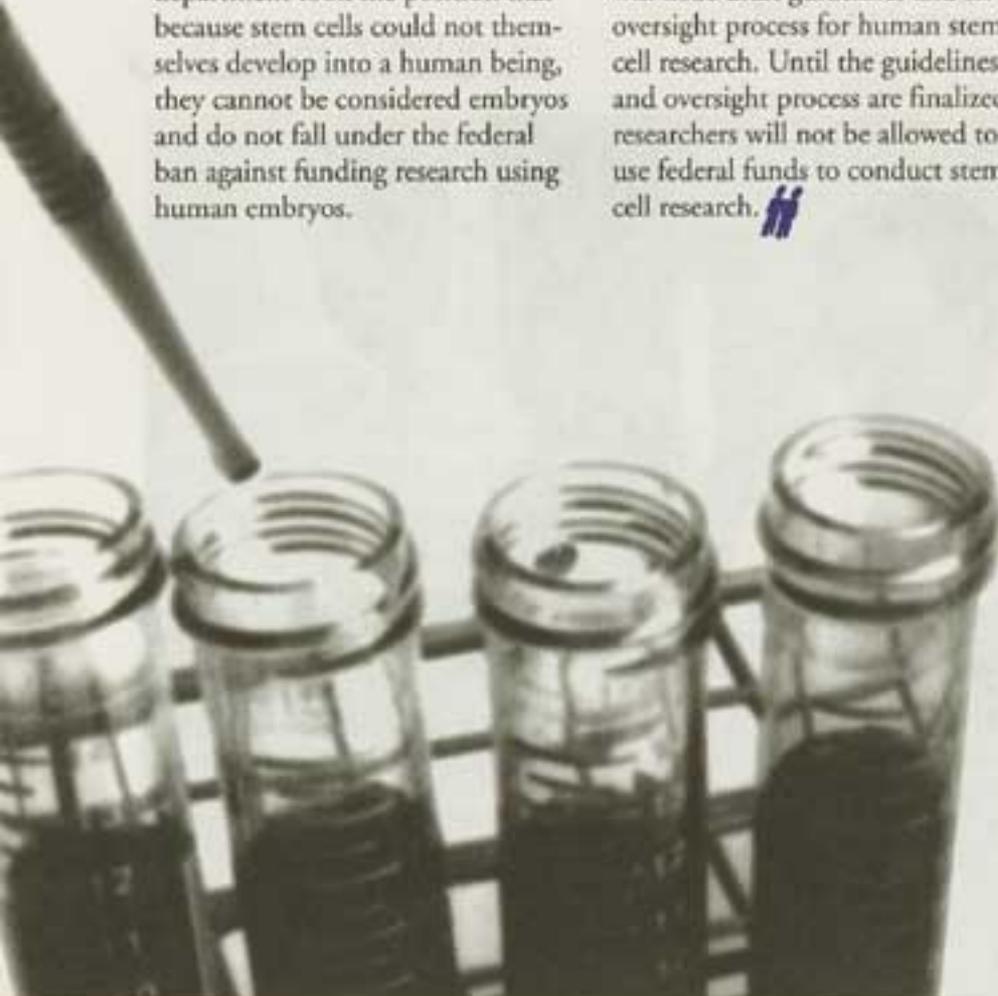
In the second experiment, a group of 11-month-old PDAPP mice that already had numerous amyloid plaques in their brains were treated with AN-1792. This group and two separate control groups similar to those used in the first experiment were evaluated after seven months, when the mice reached 18 months of age. The group that had received AN-1792 had significantly fewer plaques than the mice in the other groups.

The results from these experiments suggest two things: AN-1792 can be used as a vaccine to prevent the formation of amyloid plaques in the brains of young PDAPP mice, and AN-1792 can reduce the accumulation of amyloid plaques in the brains of older PDAPP mice.

Although the results of this study were very positive, they are still considered preliminary. Because the immune system of a mouse is very different from that of a human being, it is difficult for scientists to predict whether AN-1792 will be effective in humans.

If these findings are replicated in humans, scientists soon may be able to test AN-1792 as a potential vaccine against, as well as treatment strategy for, Alzheimer's disease.

If the vaccine is effective, however, scientists will face another test—how to identify individuals



organizations, often provide companion services.

Make the most of visits

Few long-distance caregivers are able to spend as much time with their loved one as they would like. The key is to make periodic visits and use your time effectively:

- Make appointments with your loved one's physician, lawyer, and financial adviser during your visit to facilitate decision making.
- Meet with neighbors, friends, and other relatives to hear their observations about how the person is doing. Ask if there have been any behavioral changes, health problems, or safety issues.
- Take time to reconnect with your loved one by talking, listening to music, going for a walk, or participating in activities you enjoy together.

Moving a loved one into your home

The decision to move the person to your home is influenced by many factors. Here are some things to think about before moving the person into your home:

- Does he or she want to move? What about his or her spouse?
- Is your home equipped for this person?
- Will someone be at home to care for him or her?
- How does the rest of the family feel about the move?
- How will this move affect your job, family, and finances?
- What respite services are available in your community to assist you?

Moving a person with Alzheimer's disease from familiar surroundings may cause him or her increased

agitation and confusion. You may want to talk with your loved one's physician or a social worker or call your local Alzheimer's Association chapter for assistance before making a decision. In some situations, an assisted living or a residential care setting may be a better option for the individual.

Caring for a loved one in a facility

Whether your loved one lives in an assisted living or a residential

care facility, it is important to maintain ongoing communication with the care staff and friends who visit regularly.

- Work with the managing nurse and physician. Agree on a time when you can call to get updates on the person's condition and progress.
- Call family, friends, or other visitors and ask for their observations.

SEE CARING ACROSS THE MILES, PAGE 9

Identify available support systems

There are many resources to help you locate and arrange appropriate services for your loved one.

- **Alzheimer's Association** chapters nationwide provide information on caregiving, referrals to local services, a help line, and support groups. To locate the chapter nearest you, call (800) 272-3900.
- **Geriatric care managers** can help assess the individual's needs, identify local services, and work with physicians, attorneys, and other professionals to oversee and coordinate care. For more information, call the National Association of Professional Geriatric Care Managers at (520) 881-8008.
- **Eldercare Locator** is a free service provided by the U.S. Administration on Aging to help identify local resources such as adult day programs, respite care, elder abuse/protective agencies, Medicaid information, and transportation. To learn more, call (800) 677-1116.
- **Home health care workers** can help the person with bathing, toileting, preparing meals, and taking medication. Call your local chapter of the Alzheimer's Association for more information on hiring such workers.
- **The local Area Agency on Aging (AAA)** has services to help with long-distance caregiving, such as home observation programs. Check with your local AAA to see what programs are available in your area.

Not approved
by FDA.

Consumers Prey to Health Care Marketing

Because of the devastating nature of Alzheimer's disease and the lack of a cure or truly effective treatment that can stop or reverse memory loss, affected individuals and their families often fall prey to fraudulent claims about health care products and treatments.

Hundreds of dietary supplements and herbal remedies claim to protect brain cells, "boost" memory and thinking abilities, and reverse disease symptoms in affected individuals—all claims that have yet to be scientifically proven.

Although participating in a legitimate clinical drug study might be beneficial, trying remedies that have

not been adequately researched can be dangerous since many potential side effects remain unknown. Always consult a physician before beginning a self-prescribed treatment regimen.

According to the Federal Trade Commission (FTC), consumers should be very wary about marketers who use the Internet to sell "miracle" treatments and cures to vulnerable consumers. Misleading offers could be costly to consumers' health and pocketbooks.

How to Spot False Claims

The FTC cites the following marketing techniques used to deceive consumers, including:

- The product is advertised as a

quick and effective cure-all for a wide range of ailments or for undiagnosed pain.

- The promoters use key words, such as "scientific breakthrough," "miraculous cure," "exclusive product," "secret ingredient," or "ancient remedy."
- The promoter claims the medical profession or research scientists have conspired to suppress the product.
- The advertisement includes undocumented case histories claiming amazing results.
- The product is advertised as available from only one source, and payment in advance is required.

To report a company for falsely labeling its products or a serious adverse effect associated with the use of a dietary supplement, call the FTC, your local Food and Drug Administration (FDA) office, or the state attorney general's office.

FTC's Consumer Response Center

Phone: (877) FTC-HELP

TDD: (202) 326-2505

Web site: www.ftc.gov

Adapted with permission from the Federal Trade Commission. 

- When you visit, meet with the staff members who have primary responsibility for your loved one's care.

"I make myself visible to the staff," says Levin. "I have trained them to call me about any setback Mom has in case I need to make immediate travel arrangements. It also prepares me in advance to cope with her decline."

I felt very lonely and angry because my brothers were hardly involved in my mom's care even though they live in the same area.

Resolving family conflicts

Caregiving issues can often ignite or magnify family conflicts, especially when people cope differently with caregiving responsibilities.

"This disease can be devastating to family relations," says Levin. "I felt very lonely and angry because my brothers were hardly involved in my mom's care even though they live in the same area."

Family members may deny what is happening, resent you for living far away, or

believe you are not helping enough. There may also be disagreement about financial and care decisions.

To minimize conflicts, try to acknowledge these feelings and work through them.

- Have a family meeting. Talking about caregiving roles and responsibilities, problems, and feelings can help ease tensions. You may want help from a professional counselor or clergy.
- Recognize differences. Some family members may be hands-on caregivers, responding immediately to issues and organizing resources. Others may be more comfortable with being told to complete specific tasks.
- Share caregiving responsibilities. Make a list of tasks and include how much time, money, and effort may be involved to complete them. Divide tasks according to the family member's preferences and abilities.
- Continue to communicate. Periodic family meetings or conference calls keep the family up-to-date and involved. Discuss how things are working, reassess the needs of both the person with Alzheimer's and the caregiver, and decide if any changes in responsibilities are needed.

Many long-distance caregivers feel guilty for living far away from the person with Alzheimer's. This guilt, compounded by the grief related to seeing a loved one's decline, may make it

difficult to recover emotionally from a visit. It is important to seek support from family, friends, or a counselor to help deal with these feelings.

"I need to realize that I'm doing the best I can for someone who lives 2,000 miles away," says Levin. "I'm lucky I have such understanding, supportive people around me." 



Memory Walk takes place in more than 400 communities nationwide between September 18 and October 17. To find out where and when the Memory Walk will be held in your area, call your local Alzheimer's Association chapter or (800)272-3900.

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Q & A presents answers to your research or caregiving questions from leading professionals in the field of Alzheimer's disease. Leon Thal, MD, responds to the following question about new drugs for treatment of Alzheimer's disease.

Q: I often hear about new drugs for treatment of Alzheimer's disease but then do not find them on the market right away. Once a drug has undergone testing and approval, how long does it take before the drug is available to the general public?

A: The drug development and approval process can take more than 10 years to complete. After a promising new drug undergoes several years of preclinical testing and clinical trials, the drug moves on for review by the Food and Drug Administration (FDA). The FDA's primary role is to make certain that individuals affected by various diseases are helped, rather than hurt, by new drugs.

After the clinical trials are complete, the pharmaceutical company must file a new drug application with the FDA that provides information about the drug and its chemical structure, what has been learned about the drug during testing and trials, the components and composition of the drug, how it behaves in the body, and how it is manufactured, processed, and packaged.

Once the new drug application is filed, it usually takes one to two years for approval. For Alzheimer drugs, approval may come in as little as six months because they are on the FDA's "fast-track" approval process. The order in which applications are considered is determined by a classification system that gives priority to drugs with the greatest potential benefit. For example, all drugs that offer a significant medical advance over existing therapies for any disease are considered "priority drugs." An application for a drug that duplicates a previously marketed drug product will be given less priority and will move less quickly through the process.

In the final analysis, the FDA's decision to approve, or deny approval of, a drug boils down to two questions: Do the study results provide substantial evidence of effectiveness, and do the results show that the benefits of the drug outweigh its risks?

Once the review is complete, the FDA will either approve the drug for marketing, approve it provided minor changes are made, or deny approval because of major problems. If the drug is approved, it will be available for use as soon as the firm can produce and distribute it.

It could take additional time for the drug to reach the marketplace if the drug company and the FDA do not agree on certain issues, such as the exact language that will be used in marketing the drug, the indications for the drug, and its side effects. The amount of time needed to negotiate these issues varies with the drug and with how high a priority the FDA gives to it.

Testing does not end with FDA approval. Pharmaceutical companies are required to continue submitting reports that describe new adverse reactions and important, known changes in the drug's side effects. This information helps the FDA ensure that all new drugs are effective and safe for use by the general public.

Leon Thal, MD, is the director of the Alzheimer's Disease Center at the University of California, San Diego, School of Medicine.



Send us your questions...

If you have a question you'd like to ask about Alzheimer research or care, please mail it to: Alzheimer's Association, 919 North Michigan Avenue, Suite 1100, Chicago, Illinois 60611-1676, Attn: Sara Dusenbery, or send e-mail to: sara.dusenbery@alz.org.



THE DIAGNOSIS... CONTINUED FROM PAGE 3

and his or her ability to remember, understand, talk, and do simple calculations. In early stages, screening of mental status may not detect symptoms.

- A **physical examination** includes the evaluation of a person's nutritional status, blood pressure, and pulse.
- A **neurological examination** tests the nervous system (brain and spinal cord) for evidence of other neurological disorders. A magnetic resonance imaging (MRI) study of the brain is used to search for other possible causes of dementia (e.g., stroke). In the early stages of Alzheimer's the results are often "normal" or "unremarkable."
- **Laboratory tests**, such as blood and urine tests, provide additional information about problems other than Alzheimer's that may be causing dementia.
- A **neuropsychological evaluation** tests memory, reasoning, vision-motor coordination, and language function. This evaluation may provide the only evidence of dementia, especially in the early stages.
- A **psychiatric evaluation** provides an assessment of mood and other emotional factors that could mimic dementia or that may accompany Alzheimer's disease.

Seek help from Alzheimer specialists

Your local Alzheimer's Association chapter can help you locate profes-

sionals in your area who specialize in diagnosing Alzheimer's disease.

Other resources include 29 Alzheimer's Disease Centers (ADCs) at major medical institutions nationwide. Supported by the National Institute on Aging, most ADCs offer diagnostic services and medical management (costs may vary; many centers accept Medicare, Medicaid, and private insurance). People with Alzheimer's can participate in drug trials and other clinical research projects being conducted at the centers.

"The ADCs are the best source for accessing practitioners who can assist in making the diagnosis," says Weintraub. "ADCs usually act as consultants by providing a diagnosis and follow-up care, and working side-by-side with the patient's primary care physician.

Understand the diagnosis

A diagnosis of Alzheimer's usually falls into one of the following three categories:

- A diagnosis of **probable Alzheimer's** indicates that the physician has ruled out all other disorders that may be causing dementia and has come to the conclusion that symptoms are most likely the result of Alzheimer's disease.
- A diagnosis of **possible Alzheimer's** indicates the presence of another disorder that may be affecting the known progression of Alzheimer's, so that the disease process is somewhat different than what is seen normally. In this case, however, Alzheimer's disease is still

considered the primary cause of dementia symptoms.

- A diagnosis of **definite Alzheimer's** can be made only at the time of autopsy because it requires examination of brain tissue. Autopsy confirms the presence of plaques and tangles in the brain, which are the characteristic lesions of Alzheimer's, and is the only way to diagnose the disease with 100 percent accuracy. A brain autopsy provides a vital record for your family's medical history.

The Alzheimer's Association can connect you with other resources in your community that may be helpful to you if the person is diagnosed with Alzheimer's. To locate the Association chapter in your area, call (800) 272-3900. 

Congressional Task Force on Alzheimer's Launched



Frasier star David Hyde Pierce (center) represented the Association at the announcement of an Alzheimer task force led by Representatives Smith (left) and Markey (right). As of August, 51 members of Congress have joined the task force.

In an effort to increase Congressional leaders' understanding of Alzheimer's and encourage discussion of policies related to the disease, Representative Edward Markey of Massachusetts and Representative Christopher Smith of New Jersey have formed a bipartisan task force on Alzheimer's disease.

"Like an impending hurricane, Alzheimer's is on track to wreak havoc on our nation's health care system," says Markey. "To head off this crisis, Congress needs to become more involved."

The task force will work closely with advocates from the Alzheimer's Association to address the needs of Alzheimer families.

"We will focus Congressional attention on Alzheimer research priorities, tax relief for families, and ways to reform federal health care programs, such as Medicare and Medicaid, to better assist people with the disease and their families," said Smith. 

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