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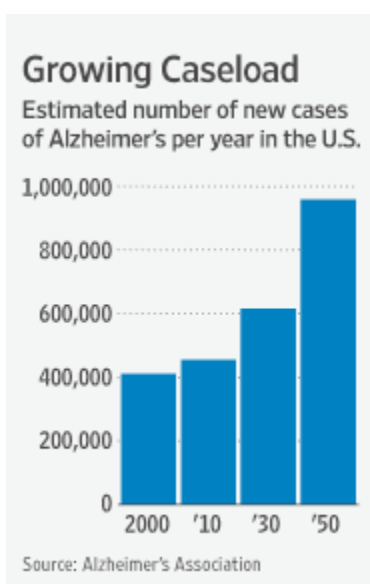
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New Tools to Detect Alzheimer's

Avid, Bayer, General Electric Push Agents to Spot the Disease From Brain Scans

By SHIRLEY S. WANG

Companies specializing in medical imaging are pushing to develop chemical agents to detect Alzheimer's disease from brain scans, a process that one day may make it possible to predict who will suffer from the progressive ailment before symptoms appear.



Credit: Getty Images

Avid Radiopharmaceuticals Inc., a tiny imaging company based in Philadelphia, and multinationals like Bayer AG and General Electric Co., are among those working on imaging compounds to help doctors spot signs of the memory-robbing disease. Such chemical compounds would be a first of their kind and would help their makers tap into the multibillion dollar Alzheimer's diagnostic market.

Currently, Alzheimer's disease can be diagnosed definitively only by taking samples of brain tissue after death and looking for signs of sticky substances called amyloid plaques. An accumulation of such plaque between brain cells is thought to contribute to the disease. However, whether the plaque causes Alzheimer's is much debated.

The imaging compounds under development are molecules with radioactive markers attached, which bind to amyloid plaques. After patients are injected with the compound, regions of the

brain take on color under scanning devices, showing where the chemical has adhered and presumably indicating Alzheimer's-related plaque.

The market for diagnosing and treating Alzheimer's is estimated to grow to nearly \$10 billion globally in 2014 from \$8 billion in 2009, according to BCC Research, a technology market research firm based in Wellesley, Mass. The diagnostics and biomarker segment alone is expected to climb to \$2.8 billion in 2014 from \$1.1 billion in 2009.

Some 7.7 million Americans older than 65 are expected to have the disease by 2030, up from 5.1 million in 2010 because of the aging population, according to the Alzheimer's Association. Currently available treatments work to treat symptoms, such as memory loss, but don't actually slow the course of the disease. Development of imaging compounds are important for increasing early detection for Alzheimer's patients, although the cost of and access to diagnostic scanning devices are concerns, according to Maria Carrillo, a neuroscientist and spokeswoman for the Alzheimer's

Association.

Doctors today must try to diagnose the disease based on their clinical assessment of the patient's memory and cognitive functioning. Some experts estimate that 15% to 20% of people labeled as Alzheimer's patients are misdiagnosed, which can lead to inappropriate treatments.

The hope is that these imaging agents will be "the first time we're able to definitively look inside someone's brain and say, 'Yeah, this is an Alzheimer's patient,' " said Richard Pither, head of research and development for GE's diagnostics division.

These diagnostic tools will be important to developing new treatments as well. Many experimental Alzheimer's treatments appear to work better in patients with less severe forms of the disease but are too weak to have an effect on patients by the time they are diagnosed today.

Closely-held Avid Wednesday presented preliminary data from a late-stage clinical trial showing that the company's compound, called florbetapir, binds to indicators of Alzheimer's in the brain and correctly identified which patients had the disease. These results, presented at the American Academy of Neurology annual conference in Toronto, were the first for this type of experimental compound in a Phase 3 trial, a key step before applying to regulators for approval of a new treatment.

The Avid trial compared the brain scans of six patients with and without memory impairment with findings from their autopsied brains after death. The correlation between the amount of amyloid detected and the brain regions where it was found by brain scans of florbetapir patients was "very strong" compared with the later autopsies, according to neuropathologist Daniel Skovronsky, Avid's chief executive and co-founder. Final results from the study are expected late this year. Because the scans are being compared with usually reliable autopsy findings, meaningful results can be obtained with relatively few subjects.

Bayer is testing florbetaben, a molecule licensed from Avid, and is also in late-stage development. Preliminary data on 150 patients in a Bayer midstage trial, presented Friday, showed that the compound correctly identified those whose doctors had also diagnosed them as having Alzheimer's disease compared with healthy patients. The company began a late-stage clinical trial at the end of 2009 that will compare brain images to autopsies; results are expected near the end of 2011, according to Bayer.

Bayer is also looking to develop molecular imaging targets for cancer, particularly certain solid tumors, as well as other neurodegenerative diseases. For Bayer's health-care division, its diagnostics and imaging unit is one of the four main areas of research and development. The German company expects peak sales of florbetaben could range from €250 million to €500 million, or about \$341 million to \$683 million a year.

Results from a midstage trial of GE's product, flutemetamol, have also been promising. Brain scans of patients using flutemetamol were found to have more amyloid plaques while healthy participants had virtually none.

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