

FDA panel sees promise in Alzheimer's imaging drug

January 20 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- A federal panel of medical experts said Thursday a first-of-a-kind imaging chemical designed to help screen for Alzheimer's disease could be useful pending additional study and training for physicians.

The [Food and Drug Administration](#) panel of advisers voted 16-0 in favor of approval for Eli Lilly's Amyvid on the condition that the company demonstrates the images can be consistently interpreted by physicians who have received training in reading the scans.

Without those requirements the panel voted 13-3 against approval for the injection in an earlier vote. The FDA is not required to follow the panel's advice, though it often does.

Amyvid is an experimental injection designed to highlight brain plaque in [medical imaging](#) scans. While panelists said the chemical helped improve visibility of the plaque, they were concerned about the widely different interpretations when doctors examined the brain scans. Panelists worried about disparate results and incorrect diagnoses in the hands of thousands of doctors across the U.S.

Alzheimer's affects 5 million seniors in the U.S. and will take an even greater toll as baby boomers move into old age. The disease attacks neurons in the brain, leading to problems with memory, thinking and behavior. There is no cure for the disease, and scientists aren't even sure what causes it.

Doctors currently diagnose the disease by observing patients and administering physical and mental tests. But researchers have argued that spotting amyloid plaque could yield earlier detection.

Amyvid, known generically as florbetapir, is an imaging agent injected into patients who are then put through a positron emission tomography, or PET, scan to detect the plaque. Eli Lilly's research suggests that a negative test for the [plaque](#) helps to rule out [Alzheimer's disease](#).

Eli Lilly and Co. paid \$300 million last year to acquire the drug and its developer, Avid Radiopharmaceuticals Inc.

Like many drugmakers, Indianapolis-based Lilly faces a wave of patent expirations in coming years that will dramatically shrink its revenue. Its top-selling product, the schizophrenia drug Zyprexa, loses patent protection later this year, exposing more than \$4 billion in annual sales to generic competition. The patent on the company's second best-seller, the antidepressant Cymbalta, loses protection in the next few years.

Company shares fell 15 cents to \$34.50 in after-hours trading.

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