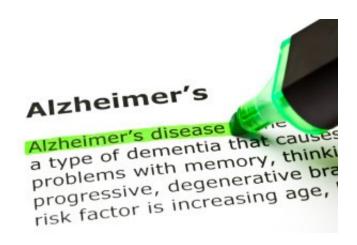


Exciting new drugs for Alzheimer's disease? Nah.

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So, exciting new drugs for treating Alzheimer's disease, right?

Wrong. Or, rather, let's allow for semi-miraculous outcomes and say instead that this recent news is unlikely to be right.

Most of the news concerned research results on two monoclonal antibody drugs reported at last week's Alzheimer's Association International Convention in Washington. Both drugs attack beta amyloid, the protein that is suspected by some researchers of gumming up the brain. Not a theory embraced by all, however.

The two drugs aren't even new drugs. Solanezumab, from Eli Lilly, has



already bombed in two previous clinical trials. Biogen reported some results from aducanumab, adding to data released in March.

There are plenty of hard-nosed critiques out there, so it's difficult to understand the media huzzahs. Unless so-called reporters are just swallowing press releases whole.

Oh, wait . . .

SOLANEZUMAB AND ADUCANUMAB: UNEVEN HISTORIES

Emily Underwood described the drugs' uneven history at Science, observing of the new results, "the <u>small cognitive benefits</u> and the fact that one trial didn't show any reduction in the amyloid in people's brains left plenty of room for skepticism."

Kevin Lomangino took stock at HealthNewsReview and noted "So why bother to present provisional results that don't even demonstrate that the drugs had any noticeable effect? As Matthew Herper points out at Forbes, the show at this week's conference may have been more about company stock prices than about informing patients and the public."

Lomangino was unhappy at pretty much all the coverage except for a piece at NBC-and even that was damaged, in his view, by a cheerleading hed. Which presumably the writer of the reasonable story had nothing to do with, as is so often the case.

At In the Pipline, pharma researcher Derek Lowe is not happy about the aducanumab study's small size. "And the first thing that has to be learned from watching clinical research (especially for a disease like Alzheimer's) is that you cannot draw conclusions until you see a large,



well-run data set. Ignore this advice at your peril. The list of promising-looking Alzheimer's ideas that have evaporated on contact with a larger trial is long and terrible."

As for solanezumab, Lowe says Lilly claims to be seeing more effect in the patients who started the therapy earlier, but "not everyone is buying that interpretation. The effect they're seeing may well be clinically meaningless."

Solanezumab failed to meet its endpoints in two Stage 3 clinical trials. Leading researchers to proclaim, in one of the more tortured arguments ever, that the disappointing outcome must mean that it works not just on symptoms but on the underlying disease itself.

Huh?

Doc Perry Wilson treats this argument with the contempt it deserves at Medpage Today, saying solanezumab is "unlikely to have any clinical benefit" and calling the announcement "a Master Class in how to spin your drug that failed its original trial."

Recent research is also showing that even if a splendid Alzheimer's drug arrives, it may be splendid for only part of the population. Frederick Kunkle reports at the Washington Post that African-Americans with Alzheimer's disease also seem to suffer from additional brain pathologies less frequent in Caucasians, notably the accumulation of abnormal proteins called Lewy bodies and lesions in tiny blood vessels.

Researchers at the Alzheimer's meeting have also found that older women with cognitive decline seem to get worse and <u>progress to Alzheimer's disease twice as fast as men</u>, Laura Geggel reports at LiveScience.



SPENDING ON ALZHEIMER'S RESEARCH

According to Harry Johns at Congress Blog, Alzheimer's is already the US's most expensive disease, one that threatens to bankrupt Medicare. Today, Medicare spends nearly 1 out of 5 of its dollars on caring for people with the disease. By 2050, a generation from now, it is estimated that will climb to nearly 1 in 3 dollars.

Neuroscientist Douglas Fields, writing at a SciAm Mind guest blog, is optimistic that even the obstructive current Congress will be open to funding more Alzheimer's research. The key, he says, will be early diagnosis. Well, maybe. But until there are effective ways of treating early Alzheimer's, early diagnosis is kinda beside the point, isn't it? Or could even be a bad idea, considering what bombshells like this hopeless news can do to patients and their families?

Bloomberg View attempts a rational economic argument for more research: "Lawmakers may also want to consider that taxpayers will end up paying either way. Medicare and Medicaid will spend \$153 billion caring for patients with Alzheimer's and other kinds of dementia this year, or about 261 times what the NIH will spend looking for ways to prevent and cure the disease. Until one is found, these numbers are way out of balance."

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