'This was the first time nobody voted for approval of a drug': Neurologist on FDA panel that negatively evaluated controversial Alzheimer's drug aducanumab resigns after agency pushes through approval

Neurologist Joel Perlmutter of Washington University in St. Louis, a member of the FDA's expert panel for nervous system therapies, told STAT in an email that he had quit the [Alzheimer's therapy Aduhelm] committee on [June 7] "due to this ruling by the FDA without further discussion with our advisory committee."

The advisory committee, which convened in November, <u>couldn't have been more openly skeptical</u> of the drug, also known as aducanumab. <u>Ten of the 11 panelists</u> found that there was not enough evidence to show it could slow cognitive decline. The 11th voted "uncertain."

But the FDA still approved the treatment on [June 7]. On top of the potentially massive implications for <u>patients</u>, <u>clinicians</u>, and <u>health care spending</u>, the decision also raised questions about the role of the advisory committees — and what it meant that the agency, in its final adjudication, bucked the very panel it had convened.

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"This isn't the first time when I was on a committee where the committee voted one way and the FDA decided another," said biostatistician Scott Emerson... "This was the first time that nobody voted for approval of this drug — nobody — and they went against that."

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