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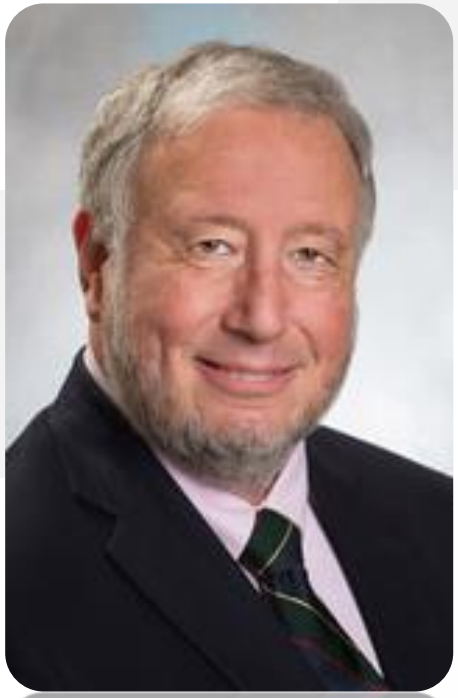

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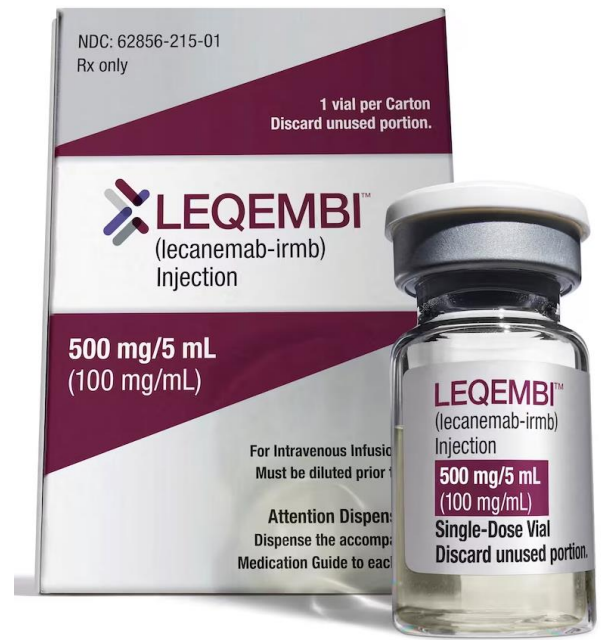
The Washington Post
Democracy Dies in Darkness

Opinion | New Alzheimer's drug is a problem for FDA's pass-fail approach

By Jerry Avorn
June 15, 2023 at 6:30 a.m. EDT

Jerry Avorn is a professor of medicine at Harvard Medical School and co-director of the Program on Regulation, Therapeutics and Law (PORTAL) at Brigham and Women's Hospital in Boston.



The Food and Drug Administration is slated to soon give full approval to Leqembi, a new medicine for Alzheimer's disease that offers only modest benefit, could pose worrisome risks and stands to cost the nation $2 billion to $5 billion per year. But the agency has an all-or-nothing problem. Even when evaluating a drug that's minimally effective or could carry considerable risks, the FDA's decision nearly always comes down to accept or reject.