Viewpoint: Why the FDA's decision to overrule its evaluatory panel and approve dementia-relief drug Aduhelm was a mistake

Like many people, I was shocked when the Food and Drug Administration ignored the advice of its neurological drugs advisory panel and broadly approved Biogen's new drug, Aduhelm.

…

[My patients] are rushing to resign from their current trials and queuing up to start Aduhelm infusions. I mentioned to them months ago that this might happen, but I never dreamed that the approval of Aduhelm would be as indefensible as has now been revealed.

…

The harm posed by Aduhelm's approval to the detriment of more promising drugs is not merely theoretical. This is already happening with galantamine — an inexpensive oral drug approved to treat Alzheimer's two decades ago.

The performance of galantamine over decades is far superior to the uninterpretable data package upon which the FDA relied in approving Aduhelm.

The FDA's baseless decision has served to focus patients, families, and clinicians on how to operationalize the approval of a costly, unreimbursed, intravenous infusion drug as patients by the hundreds or thousands reach out to their doctors asking when and how can they begin receiving it. At almost the same moment, far superior data pointing to a safe, affordable, orally active, immediately available medication are almost totally ignored.

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