



Alzheimer's drug: Aduhelm....big mistake by FDA

Prudent Prescriber's opinion on the new Alzheimer's drug. [Click here](#)

This is a well written opinion and gives the basics of all of the mistakes that the FDA has made in this decision. They did not follow the scientific process and essentially ignored the facts. Very disappointing. I fear the false hope that this decision will create for families that are already burdened with such suffering.

Good news....The FDA changed the indication for the drug from ALL patients with AD to those with MCI or Mild AD. Since those are the patients that were the subjects in the studies, at least they corrected that mistake.

Bad news.....

1. The FDA ignored the scientific process,
2. ignored the opinion of their neurology consultants (10-0 vote against approval),
3. ignored the statistics / data,
4. failed to recognize the newest research on the role of beta amyloid in dementia ,
5. and failed to recognize poor study design and multiple potential problems with these trials.

Basically, they made a decision NOT based on science and safety. I'm not sure what criteria they actually used to make this decision. It's puzzling.