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Editorial

Lessons from the Aducanumab Approval Saga

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One year ago, the US Food and Drug Administration (FDA) approved a drug that aims to degrade β-amyloid, a molecular target for the treatment of Alzheimer's disease (AD). The drug, aducanumab-a monoclonal antibody, was the first drug to be approved by the FDA in the last 20 years for treating AD. The approval of this drug through an 'accelerated approval process' came as a shock to the scientific community working in the field of neuroscience.

It was not the 'accelerated approval process' itself that shocked the most, the process is in place since 1992, primarily to expedite the approval of drugs aimed at targeting life-threatening conditions for which there are no promising drugs currently available. Many were aghast at little or no demonstrated efficacy of the drug. The results of the clinical trials did not show significant advantage to the patients. A panel of experts appointed by the FDA itself to review the trial results and make recommendations, voted almost unanimously against the approval- 10 members voting against the approval while the remaining one voting 'uncertain'. After the FDA approval of the controversial drug, three members of the panel quit in protest.

Scientists think that this debacle had undermined the integrity of the FDA. The late-stage clinical trials were incomplete and contradictory as assessed by the FDA's statistical reviewers and advisory committee. Despite that, the FDA granted approval to the drug makers. The next logical step, instead of approval, would have been another trial. Fixing the drug approval process is mandatory to restore the public trust in the FDA as a custodian of public health not only in the USA but throughout the global medical and pharmaceutical community.

It is time that the FDA recast itself as the custodian of public health by providing more transparency about its decision-making and ensuring drug companies produce information about clinical benefit. This would also minimize the risk of the FDA being considered co-opted to serve commercial interests. Furthermore, the FDA should be able to easily cancel the drug approvals if the pharmaceutical companies do not provide confirmatory evidence in due time course. The US House Committee on Energy and Commerce, which oversees drug safety and biomedical research, announced in May that it hopes to grant the FDA greater authority to rescind accelerated approvals if a company fails to complete follow-up studies on the treatment in a reasonable amount of time. This is a step in the right direction and will ensure that assessment is transparent and that companies are committed to assessing actual clinical benefit.

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