RIGHTCARE

The F.D.A.'s Aduhelm Approval: Position Statement of the Right Care Alliance September 21, 2021

The Right Care Alliance strongly opposes the recent approval by the FDA of aducanumab (Aduhelm), a drug marketed by Biogen for Alzheimer's disease. As a grassroots organization of patients, families, community members, doctors and other health workers, we are committed to putting patients, not profits, at the heart of health care and making health care institutions accountable to the communities they serve. A central part of our vision is that the conduct of medical science be of the highest possible quality and free of commercial bias and the profit motive.

We recognize that Alzheimer's disease places a massive and growing burden on patients, their families, and our communities. The lack of effective prevention or treatment causes heartache for families everywhere. But we must not let the seriousness of this disease cloud our judgement as we assess the real needs of and proper remedies for patients and their families.

The clinical trials of Aduhelm found no compelling evidence of a clinical benefit -- but they did find significant risks of bleeding and other adverse events. The FDA's decision to approve Aduhelm despite the trial findings is difficult to understand. Putting this $56,000-a-year drug on the market is going to prey on the desperation of Alzheimer's patients and their families and will drain their financial resources while putting a strain on the Medicare budget, all with no reasonable expectation of having an impact on the disease.

We note the following facts:

1. The diagnosis of early Alzheimers is quite imprecise, with very limited specificity and sensitivity when tested against progressive cognitive failure.
2. Two randomized controlled trials (RCTs) failed to show that Aduhelm provided any meaningful clinical benefit, such as improved cognition. This drug has simply not been proven to work.
3. FDA officials partnered with Aduhelm's manufacturer, Biogen, to cherry-pick certain parts of the trial data and changed the basis of its approval. Instead of showing actual improvement in patients' symptoms, the drug was approved on the basis of a reduction in amyloid plaque deposits in the brain.
4. This theory, that reducing amyloid deposits in the brain will slow a patient's cognitive decline, is unproven.
5. In the Aduhelm studies, no one over 85 was included, excluding half of the population with the onset of dementia; yet when it approved the medication, the FDA didn't include any age limitation or guidance
6. The trial patients represent only about 10% of the total population approved to get the drug and so the results are not applicable to most people who will get it.
7. The pricing model for Aduhelm includes a built-in financial incentive to prescribing doctors (and their employers) who administer the drug in the office setting (6% of the average sales price). This is in addition to the payment physicians will receive to administer the medication.
8. The FDA has required Biogen to complete a follow-up study by 2030 to answer the serious scientific uncertainties surrounding Aduhelm. But during the nine years it takes to complete that study, Biogen will be permitted to market the drug freely and to charge full price.

We note that the FDA's approval of Aduhelm will have serious consequences:

1. Accelerated approval of this drug with no clear evidence of effectiveness makes millions of people guinea pigs -- precisely the situation that the FDA was created to prevent.
2. The Aduhelm approval elevates a diagnosis around which there is no scientific consensus: "mild cognitive impairment" -- which may look the same as normal aging and opens the floodgates to off-label prescribing to millions of people who would never have progressed to clinical dementia and will now be medicated for no reason.

3. The approval opens the door to a cascade of other drug approvals based on the same faulty logic of an unproven amyloid hypothesis.
4. During the nine years it takes to complete the required study, Wall Street analysts estimate that Biogen will enjoy close to $40 billion in windfall revenues from this unproven drug.
5. The overall costs of Aduhelm will actually be higher than $56,000 per patient per year, given the multiple clinical visits and brain scans that will be required -- not to mention the costs of managing the bleeding and other adverse effects that some patients will inevitably experience.
6. With 6 million Americans suffering from Alzheimer's disease, many of them over 65, the cost of this drug and associated medical care will put pressure on Medicare's finances and rob the nation of the resources needed to improve the lives of elders and their families: money spent on useless medications cannot be spent on services that patients and families want and need, such as home health care to keep people home, transportation to maintain people's independence, or day programs to keep people active.

Aduhelm is only one of many examples of drugs that have been fast tracked for FDA approval having never been shown to be effective and causing significant harmful side effects. Although FDA regulations require companies to conduct confirmatory trials after approval for fast tracked products, in many cases these trials are delayed for years, leaving worthless, harmful and expensive drugs on the market. In other cases the FDA allows drugs to stay on the market even when confirmatory trials fail to show the drugs are effective.

We believe in the power of medical science to improve human health. We are aware that there have been remarkable achievements in therapies such as the antivirals that have saved the lives of millions of people with HIV, and other agents that have saved the lives of millions with acute and chronic leukemias. However, we cannot let these hard-won successes of the past open the door to shoddy science. The American public desperately needs a functioning FDA to protect it from the predatory practices of the pharmaceutical and biotech industries. Our political leaders of both parties have done little more than issue lofty proclamations to curb the industries' gouging of the public. We saw it and continue to see it with insulin. We see it again here. If we

don't put an end to this type of corrupted process, all of us will be paying the price far into the future.

Those of our members who are clinicians know that in our current health care system it is easier to prescribe a drug than it is to find the support systems that would make a difference in patients and families lives. The built-in incentive of the pricing model will aggravate this problem, creating inducements for MDs, the corporations that employ them, or new companies that will be created expressly to exploit this opportunity.

Those of our members who are caregivers know that false hope is a false solution to the difficult task of living with Alzheimer's disease. The main result of this approval will be the enrichment of a few individuals at the expense of many working people. Rather than treatments that do not actually work, we need a radically better system of long-term care for patients and support for families. The estimated tens of billions of dollars that Aduhelm will cost Americans is money that could be spent much more wisely on a system of right care for dementia: funding for personal care, exercise and movement therapies, music, dental, hearing and vision care, technologies like GPS anklets and alarm systems for wandering, to name just a few.

We do need more funding for all kinds of research on Alzheimer's: to find a cure if possible, but also to better understand the biology, which remains murky. For example, multiple efforts to find evidence in support of the amyloid hypothesis have failed to do so. Many cognitively normal seniors are discovered to have had amyloid plaques on autopsy. Most of all, we need to discover what helps patients and their families cope with the burden of the disease. The situation with Aduhelm is a microcosm of a fundamental problem in American healthcare: profiteering. A system of Right Care for All is the only way to realize just, affordable, and effective health care.

We demand that:

1. The Aduhelm approval be withdrawn immediately;

2. That a new RCT, designed, run, and analyzed by independent experts, paid for by new taxes on the pharmaceutical industry, be conducted before Aduhelm is considered for market approval;

3. That CMS refuse to pay for Aduhelm until such a trial is conducted and the results are analyzed;

4. That any supplies of Aduhelm made available to physicians should be for compassionate use only, provided at no cost to patients or to their insurance companies, and registered in an observational trial registry with mandatory reporting of side effects;, and that the registry database must be available to researchers and regulators in real time.

5. That the Accelerated Approval process be overhauled to prevent manipulation:
    a. accelerated approvals should not rely on surrogate biomarkers unless those biomarkers have been previously validated against meaningful clinical endpoints for the disease in question.
    b. accelerated approvals should not be granted until protocols for confirmatory trials are finalized and agreed upon;
    c. accelerated approvals should be automatically rescinded when the confirmatory trial is negative rather than left to the discretion of the pharma industry;
    d. the price of drugs sold under accelerated approvals should be capped to cover the costs of goods sold and no more until efficacy is definitively confirmed in pivotal trials

6. That the FDA be shaken up top to bottom:
    a. a new head of the FDA replacing Dr. Janet Woodcock must be someone without ties to industry and should be named immediately.
    b. That Billy Dunn, head of the neuroscience division who met improperly with Biogen executives to facilitate the approval should be relieved of his duties permanently;
    c. that Patrizia Cavazzoni, who based her approval of the drug on a personal opinion that a reduction in amyloid plaque “is expected to

lead to a reduction in the clinical decline of this devastating form of dementia" should also be relieved of her duties immediately.

7. That there be a lifetime ban on lobbying by former FDA officials who then take jobs in the drug and device industries

We conclude that without evidence of effectiveness, there is no basis for estimating a fair price for the drug, and efforts to do so perpetuate false claims of effectiveness. At $56,000 a year, the pricing of Aduhelm is predatory on taxpayers, insurers, employers, and on families without pharmaceutical coverage. We have also concluded that the FDA, by effectively benefiting the company at the expense of public safety, has corrupted its very mission.

The process we have seen unfold in the approval of Aduhelm is not isolated nor a fluke of a system that became unhinged for a brief moment. This process has been seen many times before when powerful pharmaceutical, biomedical, insurance or healthcare provider groups have lobbied (using money siphoned from the health care system) to create a system that can be manipulated for their own interests and to the detriment of society as a whole. This problem cannot be easily fixed.

We saw something similar happen when the Sackler family and Purdue Pharma created multi-billion dollars of profits from opioid drugs in one of the most devastating epidemics of the last century. It happens routinely when drug and device manufacturers get approval from the FDA to extend patent lives and make huge profits for many years by making inconsequential changes in products that provide little or no benefit to patients, often without adequate safety assessments.

Such routine practices have driven the costs of our health care system through the roof, while draining the public coffers of funding for public health. They have helped create the devastation that a virus like COVID-19 has wreaked as it rolled right over our weakened, rickety public health infrastructure. They are the hallmark of a health care system that has converted the right to be as healthy as possible into a profiteering free-for-all that is bought and sold in a marketplace in which no one can truly be an informed consumer.

The approval of Aduhelm is a symptom of a sick health care system that must be overhauled to represent the interests of all and provide the right care for all who need it, when they need it, and at a price that anyone can pay. Only a broad-based coalition of patients, providers and others willing to take action can win a new system of health, where a drug like Aduhelm, without proven value except to enrich a few at the expense of many, could never be approved.